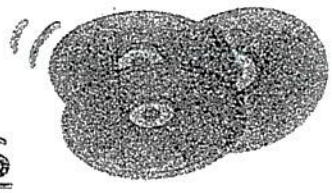
EPA REGISTRATION NUMBER 42182-9



NEW APPLICATIONS

DATE: DEC 2 3 2016

FILE REG NUMBER: 42182-0

FEP (OPPIN ENTRY): BD DEC 2 3 2016

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

SIG: _____

(Initial & Date)

FILE ROOM: _____

(Initial & Date)

ASSIGN TO PM: AD 34 RD ____ BPPD _____

_____ JACKET TO SHELF (DATA)

REVISED 11/28/12

PROCESSING REQUEST

Reg # 42182-9 **Decision #524654**

Description: Notice of Registration for Firebird F130

Electronic Label & Letter (see PPLS):	OR	**Non Electronic Label & Letter** (Scanning required):
☐ Dated:		☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Basic dated 12/23/16, Alts. #1 & #2, dated 12/23/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Lorena Rivas

Division: AD

Phone: 305-5027 **Date: 08/14/2017**

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
42182-9	8/10/2017

Term of Issuance:
Conditional

Name of Pesticide Product:
Firebird F130

Name and Address of Registrant (include ZIP Code):

Tony Herber
Mircroban Products Company
11400 Vanstory Drive
Huntersville, NC 28078

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Jacqueline Hardy, Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date: 8/10/2017

2. You are required to comply with the data requirements described in the DCI or EDSP order identified below:
    a. ADBAC GDCI-069105-30882
    b. DDAC GDCI-069149-30869
    c. DDAC GDCI-069165-30870
    d. DDAC GDCI-069166-30875

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP for more information on these proposed data requirements, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 42182-9."

4. Submit one copy of the final printed label for the record before you release the product for shipment.

5. Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance To Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

    a. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

    b. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency accepted master label.

    c. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:

        i. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.

            1. For human disease, the outbreak is listed in one of the following Centers for

Disease Control (CDC) publications:

A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)

2. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).

ii. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is [small non-enveloped, large nonenveloped, enveloped].

iii. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.

d. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 5.c.i. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 5.c. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 5.c.i., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

e. Terms 5.a through 5.d above shall become immediately void and ineffective if registration for use against [identify label viruses] is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms 5.a through 5.d above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those

claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please also note that the record for this product currently contains the following

- Basic CSF dated 12/23/2016
- Alternate Formulation #1 dated 12/23/2016
- Alternate Formulation #2 dated 12/23/2016

If you have any questions, please contact Lorena Rivas by phone at (703) 305-5027, or via email at rivas.lorena@epa.gov.

Sincerely,

Jacqueline Hardy, Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped Label
Product Chemistry Review dated 07/17/2017
Acute Toxicity Review dated 05/18/2017

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

Firebird F130

[Hospital][Disinfectant][24 Hour Residual Disinfectant][Soft Surface spot Sanitizer][Hard Surface Mildewstat][Fabric Mildewstat][Cleaner][and][Deodorizer]

KEEP OUT OF REACH OF CHILDREN
WARNING

Active Ingredients:

Alkyl dimethyl benzyl ammonium chloride (50%C_{14}, 40%C_{12}, 10%C_{16})	0.276%
Didecyl dimethyl ammonium chloride	0.104%
Octyl decyl dimethyl ammonium chloride	0.207%
Dioctyl dimethyl ammonium chloride	0.104%
Ethanol	68.610%
Other ingredients	30.699%
Total:	100.000%

EPA Reg. No.: 42182-9

EPA Est. No.: {insert appropriate EPA Est. No}
[Lot code designates actual Est.]

[Manufactured][Distributed][Sold] [by][for]:
Microban Products Company
11400 Vanstory Drive
Huntersville, NC 28078

Net contents: {Actual contents will be inserted on container label}
XX FL OZ. [(XX mL)]

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID: If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, call the National Pesticides Information Center at 1-800-858-7378. For emergencies, call the poison control center 1-800-222-1222. **EMERGENCY PHONE (24 Hours)**: 1-800-535-5053 or 1-352-323-3500.

Physical or Chemical Hazards: Combustible. Do not use or store near heat or open flame.

{For containers larger than 5 gallons, the following statement will be used}
Environmental Hazards
Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your state Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

[Can be used on] [For use on] {*Insert hard non-porous surfaces from Table x and/or x}* [and many similar household surfaces.]
[For best [aesthetics][appearance][results]]Use with a microfiber cloth [not for use with paper]

[May streak on mirrors and glass]. [For other surfaces, test in an inconspicuous area.] [Test on an inconspicuous area for colorfastness.]

Safe for use on [these] surface materials:
[plastic], [upholstery], [painted wood], [sealed wood] [painted surfaces], [washable fabric], [vinyl], [leather], [stainless steel], [aluminum], [glazed porcelain], [glazed ceramic] {or insert surface material from Table 1}

[To Refill [Trigger sprayer][Bottle]: Remove trigger sprayer. Pour in product from refill container and replace trigger.

{Sanitizing Directions}
Hold container 6"-8" from surface and spray until thoroughly wet.

> To Sanitize Hard Non-porous surfaces: Let stand 10 seconds. Wipe clean with a [damp] cloth [or sponge] [or paper towel]. Pre-clean heavily soiled surfaces. [Kills [effective against] [99.9% of] *{Insert non-food contact sanitization bacteria from Table C}*.]
>
> To spot Sanitize Soft [Fabric] surfaces: Let stand for 10 seconds. Let air dry. [For difficult odors, repeat application] [Kills [effective against] [99.9% of] *{Insert soft surface sanitization bacteria from Table D}*.]

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

{Disinfecting Directions}
TO DISINFECT Hard, non-porous surfaces: Hold container 6"-8" from surface and spray until thoroughly wet.

{one of the following statements will be used:}

Bacteria and Cold and Flu Viruses[§]: Let stand [for] 60 seconds [-or- 1 minute]

{or}

Bacteria, Enveloped viruses[□],[Rotavirus,][Fungi][and Mold and Mildew] [Mycobacteria (TB)]: Let stand [for] 3 minutes.

{or}

Bacteria, Viruses[‡],[Mycobacteria (TB)] [and] Fungi [and mold & mildew]: Let stand [for] 5 minutes.

{in conjunction with:}

Wipe with a lint free microfiber cleaning cloth [to avoid lint or paper towel residue]. Preclean heavily soiled surfaces. [Kills] [effective against] [99.9% of] {*Insert appropriate organisms from Table A based on 1, 3, or 5 minute contact time.*}

For Residual Disinfection [-or-Continuous Disinfection] on hard non-porous surfaces for 24 Hours: Hold container 6"-8" from surface. Spray [surface] ensuring [even][uniform] coverage [distribution] and thorough wetness. Allow to air dry. Preclean heavily soiled surfaces. [Kills 99.999% of][Effective Against] [bacteria] [*Staphylococcus aureus, Enterobacter aerogenes,* Methicillin Resistant *Staphylococcus Aureus* (MRSA), *Pseudomonas aeruginosa, Vancomycin resistant Enterococcus faecalis* (VRE)] . [Provides residual disinfecting activity for up to 24 hours.]

[Product [residue] can be removed by soap and water [or by re-application of the product].] [Periodic cleaning with soap and water is optional.]

Use of this product [for residual disinfection] should not alter standard cleaning and disinfection practices. If the treated surface is cleaned, reapplication of [this] product is necessary for continued residual activity.

{The following Special Instructions will only appear on final labels listing HBV, HCV, or HIV}

This product kills HBV, HCV, and HIV on precleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Hepatitis B Virus (HBV), Human Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV).

Special instructions for using this product to clean and decontaminate against HBV and HCV on surfaces/objects soiled with blood/body fluids:

Personal Protection: When handling items soiled with blood or body fluids, use disposable impervious gloves, gowns, masks and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and other objects before applying this product.

Contact Time: Allow surfaces to remain wet for 10 sec[onds], [rinse and] let air dry. For all other organisms, see directions for contact times.

Disposal of Infectious Materials: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

{Mildew Fungistatic Directions}
TO PREVENT MOLD [AND MILDEW] [growth]:

[Fabric[Soft Surface] Mildewstat] On [cotton and polyester [nonwoven]] Fabrics:
[To inhibit mold and mildew growth]: Apply to fabric surface until wet [do not saturate]. Allow to air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against *Aspergillus brasiliensis* [mildew] and *Penicillium variable*.] Pre-clean heavily soiled surfaces.

[Hard Surface Mildewstat] On hard surfaces:
[To inhibit mold and mildew growth]: Thoroughly wet surface. Allow to air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against *Aspergillus brasiliensis* [mildew]] Pre-clean heavily soiled surfaces.

{Storage and Disposal}

{For spray bottles intended to be refilled by end-user}

STORAGE AND DISPOSAL: Do Not Contaminate Water, Food, or Feed by Storage and Disposal.
STORAGE: Store out of reach of children or persons unfamiliar with its use. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. **CONTAINER HANDLING:** Do not reuse or refill except as described in the directions for use. [If not refilling,] place in trash or offer for recycling if available.

{For bottles used to refill trigger sprayer or a Nonrefillable container}

STORAGE AND DISPOSAL: Do Not Contaminate Water, Food, or Feed by Storage and Disposal.
STORAGE: Store out of reach of children and persons unfamiliar with its use. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. **CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

{NOTE: Any claim may appear on either FRONT or BACK panel in bullet or paragraph format}

{Packaging Related Claims}

- [Reduces] [packaging] waste [by X%] (when compared to regular canister or bucket or pail)
- Buy 1 Get 1 Free
- [(Bonus x%] [Bonus x fl. oz.] [X% More Free] [X fl. oz. Free]
- Packaging made with [x%] recycled plastic
- Bonus/X% More Free: [10%] [15%] [20%] [25%] [30%] More fl. ounces per bottle
- Refill Size: fills trigger sprayer 3 times
- Recyclable bottle

{Marketing Claims}

- Now -and/or- New [!] and -or- & Improved [!] {*To be used as a claim descriptor only for the first 6 months on shelf*}
- [New] [New & Improved]
- Meets OSHA blood-borne pathogens[BBP] standard
- Meets AHE hospital practice guidance for environmental cleaning
- Meets CDC guidelines for disinfection in healthcare settings
- Dual action
- No mixing, measuring, [or rinsing] required
- Ready to Use
- No need to dilute
- Non-abrasive formula
- Contains no phosphates
- Phosphate free
- [Microban®] – [Antimicrobial solutions] used by hospitals [doctors] [for over 30 years.]
- Used by hospitals [doctors] Used in hospitals. Approved [for use] in hospitals [by][doctors] [for over 30 years]
- Powered by Microban [antimicrobial] [technology]
- Saves [money][time][labor]
- Bleach free
- Chlorine free
- Manufactured in the US
- Developed in the US
- Smart cleaning product [cleaner]
- Removes and renews [regenerates][rejuvenates][refreshes]
- No accumulation [build up]
- Does not contain heavy metals
- Triclosan free
- BPA free
- Phthalates[plasticizer] free
- To be used in {insert site from Table 3}
- Will not corrode surfaces {or insert use surface from Table 3}
- Easy to use
- Convenient
- For daily use
- Versatile
- [Based on][Powered by] [Microban [antimicrobial] technology]
- Bleach-free formula [Does not contain bleach]

- [Does not include nonylphenol ethoxylates] [Does not include alkylphenol ethoxylates]
- No mixing
- No measuring
- [Sample]
- [Portable]
- [Requires no mixing or measuring and is ready-to-use]
- Cleans as it disinfects

{The following may be used on market labels for six months after introduction to market or applicable updates:}

- [long lasting][24 hour][continuous][residual] [disinfectant] [for] [healthcare]
- [Breakthrough][Innovative][Revolutionary][disinfectant][disinfecting] [technology][approach] [method] [process] [solution] [product]
- [Better] [Improved] [New] [!]
- [Better] [Improved] [New] [New and improved] [formula] [packaging] [New and improved]
- [New Claims] [New Kill Claims]
- [New Claims – Kills for 24 hours]
- [New - Saves Time]
- [New] [Residual][Persistent] Technology]
- [New] [& Improved]

{Fragrance Claims}

- No added [perfumes] [and] [or] [dyes]
- unscented
- Fresh smell
- No fragrance added
- Fragrance free

{Cleaning and Deodorizing Claims}

- [Multi-purpose cleaner]
- [Dual purpose][deodorizing][cleaning][disinfecting]
- Convenient, quick and easy cleaning all around [the office] [business] [workplace]
- [Eliminates odors]
- [Odor [elimination] [neutralization]
- Eliminates [tough] Odors
- Deodorizes [-and/or- disinfects -or- helps deodorize]
- Deodorizer
- Eliminates biological odors
- Eliminates foul smells and damp odors
- Eliminate[s] [incontinence] odors [from urine -and/or feces -and/or- vomit]
- Eliminates odors
- Eliminates odors at their source
- Eliminate odors without just masking them
- Eliminates [urinary -and/or- fecal] incontinence -or- biological –or tough odors [like urine, feces, and vomit] [quickly]
- For use on hard, non-porous surfaces -and/or- soft surfaces
- Formulated to neutralize urine -and/or feces -and/or- vomit [odors] [quickly]
- Formulated to neutralize tough -or- biological -or- [urinary -and/or fecal] [odors] [like urine -and/or feces -and/or- vomit] incontinence odors [like urine -and/or feces] [quickly]
- Leaves a pleasant fragrance

- Neutralizes odors [(doesn't [just] mask)]
- Odor eliminator
- Reduces -or- removes odors
- Removes -or- eliminates odors [quickly]
- [This effective product] eliminates odors at their source. [Does not just mask odors.]
- [This product] deodorizes areas that are hard to keep fresh smelling, in the [insert use site[s]]
- [This product] will deodorize hard, nonporous surfaces [including {insert surfaces or sites from Table 3}
- Tough lingering odors are completely removed
- Deodorizer [for institutional use]
- Deodorizes food odors [like garlic and onion] [left behind on kitchen surfaces] [after cooking]
- Odor eliminator
- Removes -or- eliminates odors
- [This effective product] eliminates odors at their source. [Does not just mask odors.]
- [This product] deodorizes areas that are hard to keep fresh smelling, in the {insert use site] from Table 3}
- [This product] will deodorize hard, nonporous surfaces [including {insert surfaces or use sites from Table 3}
- [Just][Simply][spray and wipe]

{Sanitizing Claims}

- [Rapid][Fast] [kill] [time][sanitization][Reduces][Removes][for] {insert organisms from Table C}
- [Sanitizer]
- Eliminates -or- reduces [kitchen] odors [in the trash can –or-recycling bin odors -or- smells] [caused by bacteria] Eliminates Tough Odors
- Kills odor-causing bacteria
- Kills -or- eliminates bacteria that cause [bad] odors
- Eliminates odors caused by bacteria [and non-fresh foods]
- Eliminates pet odors caused by bacteria
- Kills odor-causing bacteria in the kitchen -or- bathroom
- Kills odor-causing bacteria
- Kills -or- eliminates bacteria that cause [bad] odors

{Disinfecting Claims}

- An effective [Great][Appropriate][ideal][approach] [method] [process] [solution] [product][way] to [clean] [protect] [guard] [disinfect] [eradicate] [kill] [disinfect] [destroy] [eliminate] [against] [odor-causing] [nosocomial][Hospital borne][hospital acquired] [bacteria] [germs] [norovirus] [viruses‡] [cold & flu viruses§] [pathogens] [ESKAPE** bacteria] [harmful] [fungus] [organisms][microorganisms] on hard, non-porous surfaces[fomite] listed on this label.
- [Suitable][Approved for] [To Use] [On Surfaces[fomites]] [On {insert *item from Table 3*}]
- [Cleans and] disinfects
- Virucidal‡
- Bactericidal
- Fungicidal
- Tuberculocidal
- Perfect for disinfecting {insert use site}
- [Leaves {insert *item/use site from Table 3 }* fresh and clean]
- [Leaves [bathroom] [{insert *item/use site from Table 3}* [office] clean [and] [disinfected] [smelling fresh]
- Great][Appropriate][ideal] for cleaning [and disinfecting] around [high touch areas] [high traffic areas] [the toilet] [and] [sink] [tub]] [On {insert *item from Table 3}*
- [1 min[ute]][60 sec[ond]] [kill] [time][disinfection] for {insert organisms that are ≤1 minute contact time}

- [Easy] [and convenient] [way to clean] [and disinfect]
- Easy way to clean [and disinfect] [bathroom] [or exterior toilet surfaces] [hard, non-porous surfaces]][fomites] [So] [surfaces are more than just clean,] [they're] [disinfected]
- [Kills] [germs] [or bacteria] [that cause odor] [while it cleans]
- [3 minute kill time](excluding norovirus and poliovirus)
- [3 minute contact time](excluding norovirus and poliovirus)
- [Deactivates][Disinfectants][Kills] [cold & flu viruses[§] in 10 seconds]
- Germ fighting formula
- [Always] [ready-to-use]
- [kills all tested bacteria in 1 minute][kills bacteria in 1 minute]
- [An effective method to deodorize and disinfect against odor-causing organisms on hard non-porous surfaces]
- [An effective way to disinfect hard, non-porous environmental surfaces]
- Antibacterial
- Antimicrobial
- Helps reduce[reduces] cross contamination on treated surfaces
- [Kills [99.9%] [of germs]
- Kills germs in 1 minute *{Note to reviewer: this claim will lead to a list of at least S. aureus, P. aeruginosa, and one or more enveloped virus}*
- Disinfectant
- [Easy][convenient][to use]
- Disinfect on the go
- Can help reduce cross contamination on treated surfaces
- Clean and disinfect hard, non-porous surfaces easily
- [Use to] [Deodorize hard, non-porous surfaces] [Deodorizes, and kills common household germs]
- [Disinfect external surfaces of ultrasound transducers]
- Disinfects headsets [and telephones]
- Compatible for use on [hard non-porous] surfaces commonly found in healthcare settings [listed on this label]
- [Disinfect surfaces] [Disinfects and deodorizes in 1 minute]
- [Disinfects hard non-porous environmental surfaces listed on this label.
- [Use to]] [Disinfect against bacteria on hard, non-porous surfaces in 1 minute]
- [[Disinfects] hard surfaces [that people touch]]
- [Disinfects {insert from List 3}] [Disinfects [in [just] five [5] minutes]
- [Easy [and convenient] way to disinfect {insert use sites from Table 3}[high touch] hard, non-porous surfaces everyday]
- Effective against the flu virus[µ]
- [Effective against[bathroom] bacteria and viruses: [ESBL *E. coli*] [*Salmonella enterica*] [*Staphylococcus aureus*] [Herpes Simplex Virus Type 1] [Herpes Simplex Virus Type 2] [Hepatitis B Virus (HBV)] [Hepatitis C Virus (HCV)] [Avian Influenza A H3N2 Reassortant Virus] {insert organisms from list A}
- Effective daily cleaner
- Effectively disinfects against MRSA [Methicillin Resistant *Staphylococcus aureus*]
- Effectively disinfects against Norovirus
- [[convenient] [portable] way to disinfect hard non-porous surfaces]
- [cleaner and] disinfectant
- [Clean and disinfect in one step] [Saves Time]
- Kills ESKAPE** pathogens[organisms][in 1 min[ute]]:[*Enterococcus faecalis*VRE], [*Staphylococcus aureus*MRSA], [*Klebsiella pneumoniae* CRE], [*Acinetobacter baumannii* MDR], [*Pseudomonas aeruginosa* MBL], [*Enterobacter aerogenes*]
- [Deactivates] [Disinfectants] [kills] bloodborne pathogens in 10 seconds
- Kills TB [(Mycobacterium bovis – BCG)]
- For daily use

- For use in critical care areas [where control of cross contamination on surfaces is of prime importance]
- Helps prevent cross contamination on treated surfaces
- [Hospital [disinfectant] [disinfection] [use only when hospital use sites on label]
- Leaves [bathroom] [office]{insert use site from Table 3} disinfected [and smelling fresh]
- Odor [elimination] [neutralization] [One step cleaner and disinfectant]
- [Perfect for disinfecting exterior toilet surfaces - or - around the exterior of toilet]
- [Premixed] [Ready-to-Use] [Premeasured] [Easy] [and convenient] way to disinfect]
- [Reduces] [cross contamination] on hard non-porous surfaces
- [Wipes out] [Kills] [common] [household] [bacteria] [viruses[‡]] [germs]
- [Wipes out] [Kills] [Eliminates]: {Insert organisms from Table A} [in 1 minute]
- [Wipes out] [Kills] [the] flu virus[µ]
- [Wipes out] [Kills] [viruses[‡] and bacteria] including the flu virus[µ]
- Kills super bugs
- Peace of mind that you are eliminating [99.9%] of germs
- Reduces [nosocomial][hospital acquired][hospital borne] bacteria transmitted via contaminated surfaces
- Reduces cross contamination on treated surfaces
- Eliminates odors caused by bacteria
- Eliminates mold [and mildew] [odor[s]]
- Kills cold and flu viruses[§] in 10 seconds
- Disinfects in [1][3][5] minutes {appropriate claim will be used on container label based on which line of disinfection directions for use is used}

{24 Hour Residual Disinfection Claims}

- [Breakthrough][Innovative][Revolutionary[Only][first]][disinfectant][disinfecting] [technology][[approach] [method] [process] [solution] [product] that [is][provides]{insert any of the following bullet points from this section}

{Any of the claims below may be used alone or in conjunction with the claim above}

- Disinfection that lasts all day
- 24 hour persistence
- Persistent disinfection for [up to] 24 hours
- Enduring disinfection for [up to] 24 hours
- Hard surface persistence for [up to] 24 hours
- Designed for 24 hour disinfection against bacteria
- Provides defense against bacteria {insert bacteria from Table B}
- Maintains a disinfected surface for 24 hours
- Keeps surfaces disinfected longer to stop the spread of[nosocomial][hospital acquired][hospital borne] bacteria[pathogens]
- Protects from bacteria between each daily cleaning
- [Disinfects][Hygienic][Cleaner] between cleaning
- Guards against recontamination [after cleaning] for up to 24 hours of [nosocomial][hospital acquired][hospital borne]organisms
- 24 hour residual disinfection for {insert use site from Table 3}
- Reduce cross contamination[transmission] on [high touch] surfaces
- For [24 hour] disinfection
- [ongoing][non-stop][unabating][[Persistent][persisting][constant][sustained][long lasting][lasting][enduring][cleaning][disinfecting][persistence] for [up to] 24 hours
- [ongoing][non-stop][unabating][[Persistent][persisting][sustained]Disinfectant] for [up to] 24 hours
- [All day protection] [night and day protection][Around the clock protection]
- [lasts for 24 hrs]

- Continues to disinfect, even after the surface is dry,[giving peace of mind] for [up to] 24 hours
- [Kills all day long]][Kills and keeps killing]
- 24 hour [residual][continuous] surface disinfection against bacteria
- [This product] [Kills [*Staphylococcus aureus*] [MRSA - Methicillin Resistant *Staphylococcus aureus*][VRE *Enterococcus faecalis*]] [and][*Enterobacter aerogenes*] [*Pseudomonas aeruginosa*] for 24 hours
- [Persistent] antibacterial [disinfection] for [up to] 24 hours
- This product] eliminates 99.9[9][99]% of bacteria {insert from Table B} [for up to 24 hours]
- Disinfection that lasts all day
- [When used as directed] [this product] provides residual disinfection from {insert organisms from Table B}for [up to] 24 hours after initial application.
- Advanced residual[healthcare] disinfection
- [Independent] External tests show this formulation is scientifically proven to kill 99.9[9][99]% of bacteria for 24 hours[even after multiple touches][normal wear and tear][up to 90[96] touches][normal daily use]
- 24 hour disinfection of bacteria {insert bacteria from Table B}
- [Designed for] 24 hour disinfection [against bacteria]
- Provides defense from bacteria {insert bacteria from Table B} for 24 hours
- 99.9[99]% reduction after [90][96] touches
- Protects [-or- continuously disinfects] up to 96 touches for [up to] 24 hoursA product that gives you peace of mind for 24 hours [hr] [residual disinfection against bacteria]
- [Kills) [disinfects] [eliminates] 99.9[99]% of bacteria for 24 hours [even after multiple touches][normal wear and tear][up to 90+ touches][normal daily use]
- [This product] [kills][eliminates] 99.9% of bacteria ,then continues to disinfect [kill 99.9[99]%] against [key][common][clinically important]organisms[pathogens] {insert from Table B} for [up to] 24 hours[hrs]
- Maintains a disinfected surface for 24 hours
- Kills 99.9[99]% of bacteria {Insert organisms from Table B} for 24 hours
- Residual self-disinfecting for 24 hours
- Keeps [treated] surfaces disinfected longer to [reduce] [stop] the spread of bacteria
- Provides 24 hour residual antibacterial control [and 7 day mold & mildew prevention][even after multiple touches]
- [Disinfect] surfaces once a day to provide residual disinfection against bacteria
- Protects surfaces from bacteria between each daily cleaning [disinfecting] [with this product]
- Kills [99.9[99]%]bacteria between each daily cleaning
- Ideal for use on [in] {insert use sites/surfaces from Table 3} to provide 24 hour [antibacterial] disinfection
- [Works longer than] [lasts longer than][[standard disinfectants]
- [Unlike][Compare[d] with]][standard {insert use site from Table 3}disinfectants] continues working[disinfecting][for 24 hours][after 24 hours of touches][even when dry]
- 24 hour sustained performance even on dry treated surfaces
- Dry touch [continuous] disinfection for up to 24 hours
- Effective for longer than[standard{insert use site from Table 3}disinfectants]
- Outperforms standard hospital[healthcare] disinfectants over 24 hours
- Controls the spread of bacteria on treated surfaces for 24 hours
- Patented formula [providing residual disinfection][for [up to] 24 hours]
- Provides invisible [coating][layer] that [fights][disinfects][bacteria]for 24 hours
- Invisible film [provides disinfection][disinfects][for] 24 hours
- 24 hour disinfection on treated surfaces
- Scientifically proven [to disinfect surfaces for 24 hours]

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

{Soft Surface Sanitizer Spot Treatment}

- An [effective][fast] soft surface sanitizer
- Great for use on soft surfaces such as [insert soft surface[s] from Table 2]
- Kills microorganisms on [hospital] soft surfaces -or- fabric -or- [insert soft surface(s) from Table 2]
- No precleaning required on lightly soiled surfaces
- One-step cleaner and soft surface sanitizer
- [Removes] [Eliminates] odors by killing odor-causing bacteria on [soft surfaces] [fabrics] {insert soft surface[s] from Table 2}
- Sanitizes by killing [99.9% of] *Enterobacter aerogenes* and *Staphylococcus aureus* on soft surfaces in 10 sec[onds]
- Sanitizes fabric -or- soft surfaces -or- [insert soft surface(s) from Table 2]
- Sanitizes in one step
- Sanitizes soft surfaces [in 10 seconds][quickly][fast]
- [Rapid] Soft surface [-or- fabric] sanitizer
- Use on [couches] [chairs] [and other soft surfaces] [blinds] [curtains]
- A proven sanitizer on soft surfaces
- An effective soft surface sanitizer
- Great for use on soft surfaces such as {insert soft surfaces from Table 2}
- Kills microorganisms on [hospital] soft surfaces [fabric] {insert soft surfaces] from Table 2}
- One-step cleaner sanitizer on soft surfaces
- Use on {insert soft surfaces from Table 2}
- Effective against 100% cotton and 100% polyester fabric

{Fabric Mildewstat Claims}

- Fabric Mildewstat[fungistat]
- Controls[Inhibits][Prevents] the growth of mold [and] [mildew] for [up to] 7 days on fabric
- Controls[Inhibits][Prevents] the growth of [fungi][fungus][fungal spores][mold spores][mold & mildew spores] [for [up to] 7 days on fabric]
- Controls[Inhibits][Prevents] the growth of mold [and] [mildew] for [up to] 7 days on {Insert item from Table 2}
- Controls [inhibits] [Prevents] [mold and] mildew growth [for 7 days]
- Protects [Surfaces] [from mildew] for 7 days* *soft surfaces

{Hard Surface Mildewstat Claims}

- Prevents [mold and mildew growth][for 7 days]
- Mildewstat[fungistat]
- Controls[Inhibits][Prevents] the growth of mold [and] [mildew] for [up to] 7 days on hard surfaces
- Controls[Inhibits][Prevents] the growth of [fungi][fungus][fungal spores][mold spores][mold & mildew spores] [for [up to] 7 days on hard [bathroom][or kitchen] [or household] surfaces
- Controls[Inhibits][Prevents] the growth of mold [and] [mildew] for [up to] 7 days on {Insert items from Table 3}
- Inhibits growth of mold [& mildew] for 7 days
- Prevents [mold and mildew growth][for 7 days]

{Emerging Viral Pathogen Claims}

This product qualifies for emerging viral pathogen claims against the following categories of emerging viral pathogens when used in accordance with the directions for use for Poliovirus type 1 or Norovirus:

- Enveloped viruses
- Large non-enveloped viruses
- Small non-enveloped viruses

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

This product [-or- Product Name] has demonstrated effectiveness against viruses similar to {Insert name of emerging virus} on hard, nonporous surfaces. Therefore, this product [-or-Product Name] can be used against {Insert name of emerging virus} when used in accordance with the directions for use against {Insert name of supporting virus(es)} on hard, nonporous surfaces. Refer to the CDC -or- OIE website at {Insert pathogen-specific website address} for additional information.

{Insert name of illness/outbreak} is caused by {Insert name of emerging virus}. This product [-or-Insert Name] kills similar viruses and therefore can be used against {Insert name of emerging virus} when used in accordance with the directions for use against {Insert name of supporting virus(es)} on hard, nonporous surfaces. Refer to the {Insert CDC -or- OIE} website at {Insert pathogen-specific website address} for additional information.

{Terminal Sterilant Disclaimer per PR Notice 94-4}

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

{For product labels with veterinary/farm/animal care use sites, the following statement will be used:}

Use to disinfect and clean hard, nonporous surfaces such as feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from walls, floors, and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Pre-clean all surfaces with soap or detergent and rinse with water. Spray surface until completely wet and let stand for five (5) minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treated surfaces have been thoroughly rinsed with water and allowed to dry. Thoroughly scrub all treating, feeding, and watering appliances with soap or detergent, and rinse with potable water before re-use.

{Use Sites}

{Table 1: Hard Non-porous nonfood contact Surface Types}

Acrylic	Aluminum	Brass	Chrome
Corian®	Copper	Crystal	Glass
Formica®	Glazed porcelain [tile]	Glazed ceramic [tile]	Sealed Fiberglass
Sealed Grout	Galvanized metal	Sealed granite	Sealed [or finished] hardwood [floors]
Laminated Surfaces	Laminate	Plastic laminate	Sealed Limestone
Linoleum	Metal	Mirrors	Sealed Marble
Nickel	Plastic	Plexiglass®	PEX(cross linked polyethylene)
PVC	Sealed Slate	Sealed stone	[Stainless] steel
Sealed Terra Cotta	Sealed Terrazzo	Glazed tile	Tin
Vinyl	Painted wallboard	Finished –and/or- Painted Wood	Sealed wood
Zinc			

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

{Table 2: Soft Surface Spot Sanitizer and Fabric Mildewstat Use sites/surfaces}

Back packs	Bath[room] mat	Cotton fabrics	Chairs
[Clothing]	Mats	Exercise mats	Cloth shower curtain
Curtains	Cotton/polyester blend fabrics and textiles	Laundry bag	Diaper bag
Drapes	Stroller [seat]	Privacy drapes	Gym bags
Linens	Towels	Shades	Lab coats
Polyester fabrics	Window treatments	Scrub suits	Mattress cover
Sport equipment lining	Sports bags	textiles	

{Table 3: Hard, nonporous Use Sites/Surfaces} {May also includes graphic(s) depicting use site}

Bathroom	Dining room	Mud room	Kitchen[Δ]
Bedroom	Home[House]	Nursery	Garage
High-touch areas	Powder room	Basement	Living room
Acute Care Institutions	Bathroom Fixtures	Hotel Rooms	Assisted Living Facilities
Bathtubs	Campers	Cruise ship [surfaces] [equipment] [s]	Cruise ship surfaces
Airports	Bed [Frames] [railings]	Campground Cars	Curing Lights
Vanity top	Bed pans	Alternate Care Institutions	CAT Scan [equipment] [rooms]
Ambulance[s] [equipment] [surfaces]	Benches	Anesthesia rooms	Cutting Tools
blood glucose meters	bladder scan equipment	[Cardiac] [gym] equipment	defibrillators
Blood banks	Carts	Central Service Areas	Day Care Centers
Cervical collars	Blinds	Central Supply Rooms	Delivery Trucks
Animal Care Facilities	Dental [Chairs] [offices] [operatory rooms]	Clean rooms	Clinics
dental unit instrument trays	dopplers	infant incubators [interior and exterior surfaces of]	infant warmers [interior and exterior surfaces of]
apex locators	gurneys	[Tympanic] [Electronic] thermometers	endodontic equipment
Animal Equipment	Dialysis [Centers] [machines][clinics]	Chairs	Nurse call [button] [device]
Animal Hospitals	Boats	Changing Tables – or- Areas	Emergency vehicles
Animal Labs	Commercial Building	Hotels	Department Stores
Animal Life Science Laboratories	Bowling Alleys	Acute care institutions	Desks
Auto Repair Centers	Hospital[s] [beds]	Medical offices	Desktops
Automatic Teller Machine (ATM)	Breeding and Grooming Establishments	Computer Manufacturing Sites	Barges
Automatic Feeders	[Nylon][Hair] Brushes	Coated Mattresses	EMS & Fire Facilities
Banks	Buckets	Coated Pillows	Diaper Pails
Barber/Beauty Shops	Buses	Combs	Elder Care Centers
Bars	Newborn Nurseries	Computer keyboards	Dispensing & Filling Equipment
Basements and crawl spaces	Medical Research Facilities	Clippers	Dog/Cat Animal Kennels

Dressing Carts	Isolation [Areas] [wards]	Computer peripheral[s]	[Door] [Cabinet] [Appliance] Knobs [Frames]
Dressing Rooms	Bathroom [Counter] tops	Cabinet[s] [Cupboard[s]] [Handles]	Neonatal units
Drinking Fountains (nonfood contact areas)	Countertops$^{\Delta}$	Convenience Stores	IV [Poles][pumps]
isolettes	laboratory equipment and surfaces	loupes	operating room tables and lights
Ophthalmoscopes	Otoscopes	oxygen hoods	physical therapy (PT) equipment surfaces
Drone[s][peripherals] [equipment]	Drawer Pulls	Conveyer Belt (non-food contact)	Drain Boards
patient lift equipment	pulse oximeter	stethoscopes	telemetry equipment
telephones	Exteriors of amalgamators	Exteriors of dental curing lights	Exteriors of anesthesia machines
Exteriors of respiratory therapy equipment	Exteriors of apheresis machines	Exteriors of diagnostic equipment	Exteriors of dialysis machines
Exteriors of patient monitoring equipment	Exteriors of patient support and delivery equipment	Exteriors of pulp testers and motors	
Operating Room[s] [lights] [surfaces][tables]	Folding Tables	Hard, nonporous surfaces	Massage/Facial Salons
Ultrasonic Baths	Plastic surfaces	Appliance exteriors	Neck Braces
Ophthalmic/ Optometric facilities	Life Care Retirement Communities	Tweezers	Polyurethane keyboard covers
Recovery Room	Food Processing Plants (nonfood contact areas)	Exam [rooms] [tables]	Examination [rooms] [tables]
Respiratory Therapy centers	Food Storage Areas	Household and Automotive Garages	Mobile Homes
[Empty] Diaper Pails	Government facilities[spaces]	Housekeeping & Janitorial Rooms	Movie Houses
Grocery Carts and Stores	Footboards	Ultrasound [transducers] [and] [probes][monitors]	External surfaces of medical equipment
Equine Farms	Orthopedic Clinics	Light fixture[s]	Museums
[Surgery] [Operating] [OR] Rooms	Garbage Cans	Radiology [rooms] [equipment]	External surfaces of respiratory equipment
Polyvinyl splash aprons	Gift Shops	Mammography equipment	Hospices
Exercise Machines	Glass	Kennel Runs	Oxygen hoods
Hair/Nail/Pedicure Salons	Vet Offices or Hospitals	Kennels	Phlebotomy trays
Hair Clippers	Greenhouses	Kindergarten classrooms	Physician Offices
Finished Baseboard	Grill exteriors	Labs	Nurseries
Office[s] [Building[s]] [Equipment]	Physical therapy [rooms] [areas]	Large inflatable, non-porous plastic and rubber structures	Surgical Centers
Exterior Surfaces of Air Vents or Air Vent Exteriors	X-ray [labs] [tables] [equipment]	Laundries	Obstacle Course Play and Exercise Equipment
Manicure/ pedicure tools	Razor[s] [Trimmer] [Blades]	Vet or Veterinary Clinic Surfaces	Livestock[pork][poultry] [beef][ostrich][bison][emu] Premises
Traction Devices	Headboards	Flower Pots	
Fire Trucks	Health Clubs	Lifts	Oxygen Hoods

Flats	Sinks	Slides	Exterior surfaces of Urinals
Feed Racks	Helicopters	Litter boxes	Vanities
Public Spaces	Home Health Care	Locker Rooms	Outdoor Areas and Furniture
Photocopy Centers	Handrails	Slit Lamps	Libraries
Patio furniture	Reception Counters or Desks or Areas	Soap dispensers	Veterinary Clinics
Pedicure Basins	Recreational sporting [snow][water] equipment	Solar energy equipment[panel]	Veterinary Offices
Pens	Pet Shops	Spas	Video Stores
Performance/ Theater Centers	Recreational Facilities	Spine Backboards	Walkways
Pet Animal Quarters	Recycling Bins and Centers	Spittoons	Walls
Playpens	Shopping Malls	Sports Arenas	Washable Nail Files
Sports Complexes	Washable Walls	Stalls	Washing Areas
[Unit] Stools	Restrooms	Plumbing Fixtures	Washing machines
Trains	Restroom Fixtures	Storage areas	Watercraft
Exterior Toilet Bowl Surfaces	Retail and Wholesale Establishments	Stovetops	Wheelchairs
Piano keys	Robot[s]	Stretchers	High Touch Surfaces
Picnic Facilities	RV's	Strollers	Zoos
Pipeless Foot Spas	Satellite[s]	Supermarkets	Tools
Pipes	Salons	Tables	Touch Screen[s]
Plastic Rollers	Scales	Tack Shops	Windowsills
Playground Equipment	Schools	Surfaces of Tank Trucks	Work Areas
Playroom	Scissors	Surfaces of Tankers	Post Offices
Police Cars	Ships	Counter[top]s	Troughs
Portable and Chemical Toilets and Latrine Buckets	Recycled materials [polymers][textiles][fibers]	Trash [Barrels][Cans][Containers]	[Toilet] [Urinal] Exterior[s] [Surfaces]
Preschools	Steps	Taverns	Toy Factories
Mobile Homes	Trucks	Tires	Toilet [Seats]
TV Remote Controls	Trailers	Taxis	Refrigerator exteriors
Shower [Curtains] [doors] [stalls]	Exterior surfaces of Toilets	Telephone[s] [Booths] [Cradles]	Tanning [Beds] [equipment] [salons] [spas]
Ambulances	Ambulatory Surgical Centers (ASC)	CAT [scan] Labs	Central Supply
Critical Care Unit (CCU)	Doctors' Offices	Donation Centers [blood][plasma][semen][milk] [apheresis]	Emergency Medical Settings
Emergency Rooms (E.R.)	Emergency Vehicles	Eye Surgical Centers	Health Care Facilities
Home Health Care	Hospitals	Intensive Care Units (ICU)	Laundry Rooms
Long Term Care Centers	Neonatal Intensive Care Units (NICU)	Newborn nursery	Nursing homes
Operating Rooms (OR)	Ophthalmic Offices	Orthopedics	Out-Patient Surgical Centers (OPSC)
Patient Care Areas	Pediatrics	Pediatric Intensive Care Units (PICU)	Physical therapy
Physician's offices	Rehabilitation	Respiratory therapy	Skilled Nursing Facility
Surgery [rooms]	Surgery Intensive Care Unit (SICU)	Surgical Centers	Transport vehicles

X-Ray [rooms][equipment]			

{Table A: List of Disinfection Organisms}

Disinfection

Contact Time	Bacteria	Identification Number	Antibiotic Resistance demonstrated
1 min[ute]	***Acinetobacter baumannii* MDR (Multi-drug resistant)	[ATCC BAA-1605]	[Ceftadizime, Gentamicin, Ticarcillin, Piperacillin, Cefepime, Ciprofloxacin, Imipenem, Meropenem]
	***Enterobacter aerogenes*	[ATCC 13048]	
	Escherichia coli ESBL (Extended spectrum beta-lactamase)	[ATCC BAA-196]	[Ceftadizime, Cefotaxime]
	Escherichia coli O157:H7	[ATCC 35150]	
	***Enterococcus faecalis* VRE (Vancomycin resistant enterococcus)	[ATCC 51575]	[Vancomycin]
	***Klebsiella pneumoniae* CRE (Carbapenem resistant Enterobacteriaceae)	[ATCC BAA-2146]	[Imipenem, Meropenem]
	Pseudomonas aeruginosa	[ATCC 15442]	
	***Pseudomonas aeruginosa* MBL (Metallo beta-lactamase positive)	[CDC AR-0246/PSA-18]	[Imipenem]
	Salmonella enterica	[ATCC 10708]	
	Staphylococcus aureus	[ATCC 6538]	
	***Staphylococcus aureus* (Methicillin Resistant) (MRSA)	[ATCC 33592]	[Methicillin]
	Staphylococcus epidermidis (Methicillin Resistant) (MRSE)	[ATCC 51625]	[Methicillin]
	Staphylococcus aureus (VISA) (Vancomycin-Intermediate)	[HIP5836]	[Vancomycin]
	Staphylococcus aureus (VRSA) (Vancomycin-Resistant)	[HIP11714]	[Vancomycin]
	Fungi		
3 min[ute]	*Aspergillus brasiliensis*	[ATCC 6275]	
	Candida albicans	[ATCC 10231]	
	Trichophyton interdigitale	[ATCC 9533]	
	Enveloped Viruses	**Reference No.**	**Strain Information**
10 sec[ond]	‡□Hepatitis B Virus (HBV) (Duck Hepatitis B Virus [as surrogate])		[11/4/12]
	‡□Hepatitis C Virus (HCV) (Bovine Viral Diarrhea Virus [as surrogate])		[Oregon C24v-genotype 1]
	‡□Herpes simplex virus type 1	[ATCC VR-733]	[F(1)]
	‡□Herpes simplex virus type 2	[ATCC VR-734]	[G]
	‡□Human Coronavirus§	[ATCC VR-740]	[229E]
	‡□Human Immunodeficiency virus type 1 (HIV)		[HTLV-III_B]
	‡□Avian Influenza A (H3N2) Reassortant virus§,µ	[ATCC VR-2072]	[A/Washington/897/80 x A/Mallard/New York/6750/78]

	‡□2009-H1N1 Influenza A virus§,µ [(Novel H1N1)]	[CDC 2009712192]	[A/Mexico/4108/2009]
	‡□Respiratory syncytial virus (RSV)§	[ATCC VR-26]	[Long]
	Large Non-enveloped Viruses		
2 min[ute]	‡Rotavirus	[ATCC VR-2018]	[WA]
	Small Non-enveloped Viruses		
5 min[ute]	‡Poliovirus type 1	[ATCC VR-1562]	[Chat]
	‡Norovirus (Feline Calicivirus as surrogate)	[ATCC VR-782]	[F-9]
	Mycobacteria		
3 min[ute]	*Mycobacterium bovis* – BCG [(TB)] (68.2°F)[20.1°C]		

{Table B: List of Residual Disinfection Organisms}

Residual Disinfection

Contact Time	Bacteria	Identification Number	Antibiotic Resistance demonstrated
5 min[ute]	*Enterobacter aerogenes*	[ATCC 13048]	
	Enterococcus faecalis VRE (Vancomycin resistant enterococcus	[ATCC 51575]	[Vancomycin]
	Pseudomonas aeruginosa	[ATCC 15442]	
	Staphylococcus aureus	[ATCC 6538]	
	Staphylococcus aureus (Methicillin Resistant) (MRSA)	[ATCC 33592]	[Methicillin]

{Table C: List of Nonfood Contact Surface Sanitization Organisms}

Hard, Nonporous Non-food Contact Surface Sanitization

Contact Time	Bacteria	Identification Number
10 sec[ond]	*Enterobacter aerogenes*	[ATCC 13048]
	Staphylococcus aureus	[ATCC 6538]

{Table D: List of Soft Surface Sanitization Organisms}

Soft Surface Spot Sanitization

Contact Time	Bacteria	Identification Number
10 sec[ond]	*Enterobacter aerogenes*	[ATCC 13048]
	Staphylococcus aureus	[ATCC 6538]

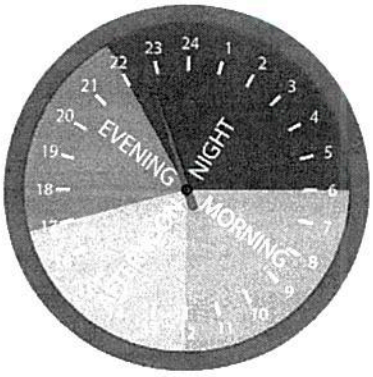
{Table E: List of Mildew Fungistatic Organisms}

Mildew Fungistat

Duration	Surface	Bacteria	Identification Number
7 days	Hard Surfaces	*Aspergillus brasiliensis*	[ATCC 6275]
	Soft (Fabric) Surfaces	*Aspergillus brasiliensis*	[ATCC 6275]
		Pencillium variabile	[ATCC 32333]

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

{Optional Pictograms- Usage and Use Sites/Surfaces}

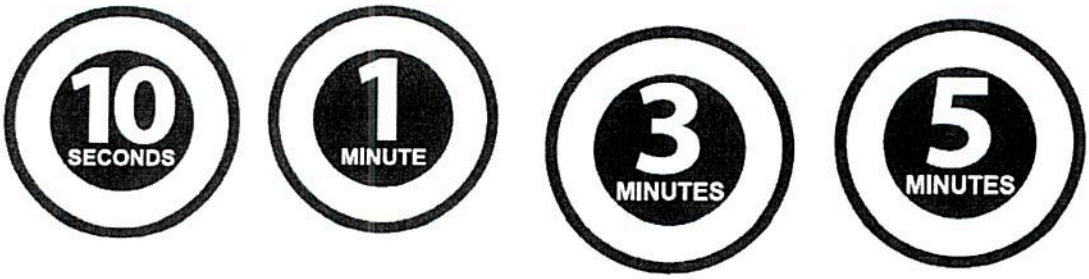


MICROBAN
ELEVATE

PROTECTION THAT LIVES ON
MICROBAN

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

{The following graphics may incorporate a claim from the list of disinfection claims on pages 7-9}



{The following graphics may incorporate a claim from the list of residual disinfection claims on pages 9-10}

Rivas, Lorena

From: Tran, Tiffany
Sent: Monday, August 14, 2017 2:10 PM
To: Rivas, Lorena
Cc: Hardy, Jacqueline; OPP AD QAQC
Subject: QA/QC - 42182-9
Attachments: 42182-9-20170810.pdf

Pass. The above product has passed the quality control check. Please print the e-signed letter/e-stamped label(attached) file the hard copy in the jacket, and return the jacket to the file room. If your action included a CSF, fill out the Data Extraction Request Form. Thank you

Thank you,

Tiffany Tran
US Environmental Protection Agency
Office of Pesticide Programs
Antimicrobials Division
Regulatory Management Branch II
703-347-0414

SUBMITTED VIA CDX

December 23, 2016

Ms. Jacqueline Hardy, PM-34
U.S. Environmental Protection Agency
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

SUBJECT: Firebird F130, EPA Reg. No. 42182-x

Dear Ms. Hardy:

On behalf of Microban Products Company (Microban), we enclose a submission for the above referenced product. Scientific & Regulatory Consultants, Inc. is the agent of record for Microban. Firebird F130 is a ready to use (RTU) hard surface disinfectant with 24 hour residual disinfection claims for use in healthcare settings. The product is also a nonfood contact surface sanitizer and sanitizer for soft (fabric) surfaces.

This submission is for a new end use product; FIFRA §2(mm) uses, and thus qualifies for PRIA code A540 with a 5 month review period and PRIA fee of $5,107. Due to the large number of efficacy studies submitted, prior correspondence with the Agency is attached indicating a 2 month extension to the PRIA timeline will be required. Proof of PRIA payment via www.pay.gov is enclosed.

Studies supporting 24 hour residual disinfection against bacteria were conducted in accordance with Microban's Agency-approved protocol (EPA File symbol 42182-PA-3). As the protocol utilizes a qualitative method requiring a 5 log reduction, the studies support claims of 99.999% reduction for 24 hours.

Acute Toxicity:
Testing was conducted in accordance with the required guidelines. The acute "6-pack" is included. A certificate of analysis for the test material indicating the active ingredients concentrations is included in each study report. Also included is a Toxicity Discussion Volume (Volume 14, MRID 50118914) which contains correspondence with EPA (K. Hicks) regarding the dermal sensitization study OCSPP 870.2600 found in Volume 13, MRID 50118913.

Efficacy:
Relevant efficacy studies are submitted to allow the product label to claim hard, nonporous surface disinfection (including supplemental bacterial, fungal, mycobacteria, and viral claims), hard, nonporous surface residual disinfection (against bacteria), hard, nonporous surface sanitization, soft (fabric) surface sanitization, and mildewstatic properties for hard and fabric surfaces. The lots used in efficacy testing were formulated with the active ingredients at or below their respective lower certified limits. The chemical characterization reports (certificates of analysis) for the lots used in each test are included in each efficacy report.

Product Chemistry:
Two alternate Confidential Statements of Formula (CSFs) are included. They differ from the basic formulation by [redacted] A corresponding [redacted] as the balance of the formula) also occurs.

A request for [redacted] inert ingredient is located in MRID 50118901, along with justification to support this request.

Test Material Name:
All testing was conducted using the same formula. In some reports the formula is reported as "Firebird F-130" and in others as "Firebird F130" or "Mircoban F130". These three names all represent the same formula.

We look forward to a timely review of this submission. If you need any clarification or issues arise during the review of this information, please contact me immediately via phone (260-244-6270) or email (therber@srcconsultants.com) for resolution. Please use therber@srcconsultants.com for all milestone tracking emails.

Sincerely,

Tony Herber
Agent for Microban Products Company

cc: Gina Sloan, Microban Products Company

Attachment 1 – Correspondence with EPA (J. Hardy) – 2 month PRIA Extension

201 W Van Buren Street
Columbia City, IN 46725

www.srcconsultants.com

P: 260.244.6270
F: 260.244.6273

Firebird F130

EPA File Symbol 42182-x

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

   Scientific & Regulatory Consultants, Inc.
   201 W Van Buren Street
   Columbia City, IN 46725

   AGENT FOR:
   Microban Products Company
   11400 Vanstory Drive
   Huntersville, NC 28078

2. Regulatory action in support of which this package is submitted:
   New end use product; FIFRA §2(mm) uses only
   PRIA Code A540, PRIA fee $5,107

3. Transmittal date:

   December 23, 2016

4. Administrative materials:

   A) Cover letter ✓
   B) Form 8570-1: Pesticide Application ✓
   C) Pay.gov PRIA payment confirmation for $5,107 (Pay.gov ID 25VIOSC4)
   D) Form 8570-4: Confidential Statement of Formula: Basic and Alternates 1 & 2 dated 12/23/16 ✓
   E) Form 8570-27: Formulator's Exemption Statement ✓
   F) Form 8570-34: Certification with Respect to Citation of Data (2) ✓
   G) Form 8570-35: Data Matrix – End-Product (Agency and Public copies) ✓
   H) Form 8570-35: Data Matrix – TGAI (Agency and Public copies) ✓
   I) Proposed Master Label ✓

5. Vol. 1 Product Chemistry (MRID 50118901)
   OCSPP 830.1550-1800 Product Chemistry: Identity, Composition, and Analysis

6. Vol. 2 Product Chemistry (MRID 50118902)
   OCSPP 830.6302-7300 Product Chemistry Testing; A19784

7. Vol. 3 Product Chemistry (MRID 50118903)
   OCSPP 830.1700 Preliminary Analysis; A19783

8. Vol. 4 Product Chemistry (MRID 50118904)
   OCSPP 830.1800 Enforcement Analytical Titration Validation for Chemical Characterization; A18255

9. Vol. 5 Product Chemistry (MRID 50118905)
   OCSPP 830.1800 Enforcement GC Method Validation for Chemical Characterization; A18248

10. Vol. 6 Product Chemistry (MRID 50118906)
    OCSPP 830.6317 & 830.6320 Accelerated Storage Stability of Test Substances; A19131

11. Vol. 7 Product Chemistry (MRID 50118907)
OCSPP 830 Series Product Chemistry Data Waivers

12. Vol. 8 Toxicity (MRID 50118908)
OCSPP 870.1100 Acute Oral Toxicity (UDP) in Rats; 19136-15

13. Vol. 9 Toxicity (MRID 50118909)
OCSPP 870.1200 Acute Dermal Toxicity in Rats; 19137-15

14. Vol. 10 Toxicity (MRID 50118910)
OCSPP 870.1300 Acute Inhalation Toxicity in Rats; 19138-15

15. Vol. 11 Toxicity (MRID 50118911)
OCSPP 870.2400 Acute Eye Irritation in Rabbits; 19139-15

16. Vol. 12 Toxicity (MRID 50118912)
OCSPP 870.2500 Acute Dermal Irritation in Rabbits; 19140-15

17. Vol. 13 Toxicity (MRID 50118913)
OCSPP 870.2600 Skin Sensitization in Guinea Pigs; 19141-15

18. Vol. 14 Toxicity (MRID 50118914)
OCSPP 870 Series Toxicity Discussion Volume

19. Vol. 15 Efficacy (MRID 50118915)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus aureus* (ATCC 6538); GLP1573

20. Vol. 16 Efficacy (MRID 50118916)
OCSPP 810.2200 AOAC Germicidal Spray Method – *Pseudomonas aeruginosa* (ATCC 15442); A20096

21. Vol. 17 Efficacy (MRID 50118917)
OCSPP 810.2200 AOAC Germicidal Spray Method – *Salmonella enterica* (ATCC 10708); A20094

22. Vol. 18 Efficacy (MRID 50118918)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Acinetobacter baumannii* (MDR) (ATCC BAA-1605); GLP1479

23. Vol. 19 Efficacy (MRID 50118919)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Enterobacter aerogenes* (ATCC 13048); GLP1434

24. Vol. 20 Efficacy (MRID 50118920)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Enterococcus faecalis* (VRE) (ATCC 51575); GLP1582

25. Vol. 21 Efficacy (MRID 50118921)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Escherichia coli* (ESBL) (ATCC BAA-196); GLP1478

26. Vol. 22 Efficacy (MRID 50118922)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Escherichia coli* (O157:H7) (ATCC 35150); GLP1477

27. Vol. 23 Efficacy (MRID 50118923)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Klebsiella pneumoniae* (CRE) (ATCC BAA-2146); GLP1476

28. Vol. 24 Efficacy (MRID 50118924)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus aureus* (MRSA) (ATCC 33592); GLP1583

29. Vol. 25 Efficacy (MRID 50118925)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus epidermidis* (MRSE) (ATCC 51625); GLP1598

30. Vol. 26 Efficacy (MRID 50118926)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus aureus* (VRSA) (HIP11714); GLP1599

31. Vol. 27 Efficacy (MRID 50118927)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus aureus* (VISA) (HIP5836); GLP1600

32. Vol. 28 Efficacy (MRID 50118928)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Pseudomonas aeruginosa* MBL (CDC AR-0246/PSA-18); GLP1558

33. Vol. 29 Efficacy (MRID 50118929)
OCSPP 810.2200 Fungicidal Germicidal Spray Method – *Trichophyton mentagrophytes* (ATCC 9533); A21241

34. Vol. 30 Efficacy (MRID 50118930)
OCSPP 810.2200 Fungicidal Germicidal Spray Method – *Aspergillus niger* (ATCC 6275); A21500

35. Vol. 31 Efficacy (MRID 50118931)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Candida albicans* (ATCC 10231); GLP1596

36. Vol. 32 Efficacy (MRID 50118932)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus; A20898

37. Vol. 33 Efficacy (MRID 50118933)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus; A20925

38. Vol. 34 Efficacy (MRID 50118934)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 1; A21016

39. Vol. 35 Efficacy (MRID 50118935)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 2; A21015

40. Vol. 36 Efficacy (MRID 50118936)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Coronavirus; A20995

41. Vol. 37 Efficacy (MRID 50118937)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Immunodeficiency Virus type 1; A21002

42. Vol. 38 Efficacy (MRID 50118938)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Avian Influenza A (H3N2) Reassortant virus; A20567

43. Vol. 39 Efficacy (MRID 50118939)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – 2009-H1N1 Influenza A virus (Novel H1N1); A20994

44. Vol. 40 Efficacy (MRID 50118940)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus; A20534

45. Vol. 41 Efficacy (MRID 50118941)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Poliovirus type 1; A21684

46. Vol. 42 Efficacy (MRID 50118942)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Respiratory syncytial virus (RSV); A21001

47. Vol. 43 Efficacy (MRID 50118943)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rotavirus; A21683

48. Vol. 44 Efficacy (MRID 50118944)
OCSPP 810.2200 AOAC Tuberculocidal Activity of Disinfectant Spray Products – *Mycobacterium bovis* - BCG; A19362

49. Vol. 45 Efficacy (MRID 50118945)
OCSPP 810.2200 Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – *Enterobacter aerogenes* (ATCC 13048), *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538); A19382

50. Vol. 46 Efficacy (MRID 50118946)
OCSPP 810.2200 Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575); A19778

51. Vol. 47 Efficacy (MRID 50118947)
OCSPP 810.2200 Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592); A19779

52. Vol. 48 Efficacy (MRID 50118948)
OCSPP 810.2300 Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application) – *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538); A21548

53. Vol. 49 Efficacy (MRID 50118949)
OCSPP 810.2400 Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application) – *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538); A21260

54. Vol. 50 Efficacy (MRID 50118950)
Subdivision G, 93-30 EPA Hard Surface Mildew-Fungistatic Test – *Aspergillus niger* (ATCC 6275); A20568

55. Vol. 51 Efficacy (MRID 50118951)
Subdivision G, 93-30 Fabric Mildew Fungistatic Test – *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333); A20284

Company Official:	Tony Herber
Company Name:	Agent – Microban Products Company
Company Contact:	Tony Herber, Phone (260) 244-6270 Email: therber@srcconsultants.com

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060, Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☑ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
42182-x	J. Hardy	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Firebird F130	34	

5. Name and Address of Applicant *(Include ZIP Code)*

Microban Products Company
11400 Vanstory Drive
Huntersville, NC 28078

☐ *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☑ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New product submission
PRIA Category: A540; new end-use product, existing chemical, requiring science review for product chemistry, acute toxicity, and efficacy.
PRIA Fee: $5,107 (Pay.gov ID 25VIOSC4); e-mail address: therber@srcconsultants.com, phone: 260.244.6270.
See cover letter for more details.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	16, 24, 32, 64 fl. oz., 1, 5, 55, 275 gal	☑ on label

6. Manner in Which Label is Affixed to Product ☑ Lithograph ☑ Paper glued ☐ Stenciled ☑ Other shrink sleeve, pressure sensitive

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Tony Herber	Agent	(260) 244-6270

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingllly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	
Tony Herber	Agent	
4. Typed Name	**5. Date**	
Tony Herber	12/23/2016	

Rivas, Lorena

From: Ricciardi, Rachel
Sent: Thursday, August 10, 2017 8:34 AM
To: Rivas, Lorena
Cc: Williams, Sanyvette
Subject: RE: need your assistance wih a PRIA.

Hi Lorena!

Sure, so there are reregistration GDCIs & PDCIs that went out to ADBAC & DDAC (below). Data is still outstanding.

ADBAC
GDCI-069105-30882
PDCI-069105-30933

DDAC
GDCI-069149-30869
PDCI-069149-30855

GDCI-069165-30870
PDCI-069165-30857

GDCI-069166-30875
PDCI-069166-30858

The reg review ADBAC/DDAC GDCIs haven't been issued yet, as we're waiting for OMB approval before we issue them. Hopefully those will be issued by the end of this quarter or if not then at least by the end of the calendar year.

As for ethanol, there are rereg GDCIs/PDCIs that were issued back in 1994/1995, so all of the data should definitely have been fulfilled by now. For reg review, ethanol is part of the Aliphatic Alcohols, C1-C5 case and there are no GDCIs that were issued, as the case did not require more data to be called in. This is SanYvette's case so I'm copying her on this email in case I got anything incorrect, but I checked in my team's Access Database for the reg review info & OPPIN Data Entry for the rereg DCIs, so everything should be correct!

Ethanol
GDCI-001501-17540
PDCI-001501-0119

I hope this helps! ☺
-Rachel

From: Rivas, Lorena
Sent: Thursday, August 10, 2017 8:14 AM
To: Ricciardi, Rachel <Ricciardi.Rachel@epa.gov>
Subject: need your assistance wih a PRIA.

Good morning lady,

Im working on this PRIA due date is this coming Friday. For the following five actives, can you please tell me if there's data requirements are there any DCI or GDCIs???

1. Alkyl dimethyl benzyl ammonium chloride 069105
2. Didecyl dimethyl ammonium chloride 069149
3. Octyl decyl dimethyl ammonium chloride 069165
4. Dioctyl dimethyl ammonium chloride 069166
5. Ethanol 001501

Thank you for your assistance. ☺

Lorena Rivas
Registration Risk Manager
Antimicrobials Division (AD)
Environmental Protection Agency
2777 South crystal Drive
Arlington, VA 22202
Rivas.lorena@epa.gov

Decision #: 524654
DP #: (437786)
PRIA
Parent DP #:
Submission #: 996811
E-Sub #: 16351

DA. PACKAGE BEAN SHEET

Date: 27-Jan-2017

* * * Registration Information * * *

Registration: 42182-O - Firebird F130

Company: 42182 - MICROBAN PRODUCTS COMPANY

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date: _____ PRIA Due Date: ~~13-Jun-2017~~ Aug. 13, 2017 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: See page 3

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 27-Jan-2017 Due Back: _____

DP Ingredient: See page 3

DP Title: Efficacy Ibrahim

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	AD / PSB			Last Possible Science Due Date: 14-May-2017
Team Name:	EET			Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

New Hospital Disinfectant
Electronic Submission: Please go to Documentum for Info

Science Technical Screen due date: 2/20/201
(Note: Registrant requested 2 month extension to compensate for number of studies)
Please review studies, 50118915 -05011895[illegible], for completeness

Evaluation
Please review the efficacy data to determine if it supports the claims on the proposed label

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

July 31, 2017

MEMORANDUM

Subject: Efficacy Review for Firebird F-130, EPA File No. 42182-O; DB Barcode: D437786; E-Sub #: 16351.

From: Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Hardy RM 34 / Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Microban Products Company
11400 Vanstory Drive
Huntersville, NC 28078

Formulation from the Label:

Active Ingredient	% by wt.
Alkyl dimethyl benzyl ammonium chloride ($50\%C_{14}$, $40\%C_{12}$, $10\%C_{16}$)	0.276 %
Didecyl dimethyl ammonium chloride	0.104 %
Octyl decyl dimethyl ammonium chloride	0.207 %
Dioctyl dimethyl ammonium chloride	0.104 %
Ethanol	68.610 %
Other Ingredients	30.699 %
Total	100.000 %

I. BACKGROUND

The applicant has requested to register a proposed product, Firebird F-130 (EPA File No. 42182-O), as a ready to use, hard surface cleaner/disinfectant (bactericide, fungicide, tuberculocide, virucide), with 24-hour residual disinfection claims for use in healthcare settings. Also requested are non-food contact surface sanitizer and soft (fabric) surface sanitizer claims, in addition to mildewstatic claims for hard, non-porous and fabric surfaces. Supporting efficacy studies were conducted by Microchem Laboratory, Round Rock, TX and by Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package identified as D437786 contained letters from the applicant's representative to the Agency (dated December 23, 2016), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-27 (Formulator's Exemption Statement), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), thirty-seven efficacy studies (MRID Nos. 501189-15 through and 501189-51), Statement of No Data Confidentiality Claims for the studies, and the proposed product label (Version 122216).

II. PROPOSED USE DIRECTIONS

Sanitizing Directions

Hold container 6"- 8" from surface and spray until thoroughly wet[treated].
To Sanitize Hard Non-porous surfaces: Let stand 10 seconds. Wipe clean with a [damp] cloth [or sponge] [or paper towel]. Pre-clean heavily soiled surfaces. [Kills [effective against] [99.9% of] {Insert non-food contact sanitization bacteria from Table C}.]
To [spot] Sanitize Soft [Fabric] surfaces: Let stand for 10 seconds. Let air dry. [For difficult odors, repeat application] [Kills [effective against] [99.9% of] {Insert soft surface sanitization bacteria from Table D}.]

Disinfecting Directions

TO DISINFECT Hard, non-porous surfaces: Hold container 6"-8" from surface and spray until thoroughly wet[treated].
{one of the following statements will be used:}
Bacteria and Cold and Flu Viruses§: Let stand [for] 60 seconds [-or- 1 minute]
{or}
Bacteria, Enveloped viruses☐ [Rotavirus,][Fungi][and Mold and Mildew] [Mycobacteria (TB)]: Let stand [for] 3 minutes.
{or}
Bacteria, Viruses‡,[Mycobacteria (TB)] [and] Fungi [and mold & mildew]: Let stand [for] 5 minutes. {in conjunction with:}
Wipe with a lint free microfiber cleaning cloth [to avoid lint or paper towel residue]. Preclean heavily soiled surfaces. [Kills] [effective against] [99.9% of] {Insert appropriate organisms from Table A based on 1, 3, or 5 minute contact time.}

TO DISINFECT hard non-porous surfaces for 24 Hours: Hold container 6"- 8" from surface and spray until thoroughly [-or-visibly] wet[treated]. Wipe to ensure there is [even][uniform] coverage and allow to air dry. Preclean heavily soiled surfaces. [No rinsing required]. [Kills 99.999% of][Effective Against][bacteria] [Staphylococcus aureus, Enterobacter aerogenes, Methicillin Resistant Staphylococcus Aureus (MRSA), Pseudomonas aeruginosa, Vancomycin resistant Enterococcus faecalis (VRE)]. [Provides residual disinfecting activity for up to 24 hours.]
[Product [residue] can be removed by soap and water [or by re-application of the product].] [Periodic cleaning with soap and water is optional.]

Mildew Fungistatic Directions

TO PREVENT MOLD [AND MILDEW] [growth]:
[Fabric [Soft Surface] Mildewstat] On [cotton and polyester [nonwoven]] Fabrics:
[To inhibit mold and mildew growth]: Apply to fabric surface until wet [do not saturate]. Allow to air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against Aspergillus niger [mildew] and Penicillium variable.] Pre-clean heavily soiled surfaces.
[Hard Surface Mildewstat] On hard surfaces:
[To inhibit mold and mildew growth]: Thoroughly wet surface. Allow to air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against Aspergillus niger [mildew]] Pre-clean heavily soiled surfaces.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different product lots at the LCL, against Staphylococcus aureus ATCC 6538 (for effectiveness against Gram-positive bacteria), and Pseudomonas aeruginosa ATCC 15442 (representative of a nosocomial pathogen), [120 carriers per sample; a total of 360 carriers]. To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required in AOAC Germicidal Spray Products Test to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for Staphylococcus aureus ATCC 6538; 57 out of each set of 60 carriers for Pseudomonas aeruginosa ATCC 15442. Performance requirements when using AOAC Use-Dilution Method are killing in 57 out of each set of 60 carriers for Staphylococcus aureus ATCC 6538 and 54 out of each set of 60 carriers for Pseudomonas aeruginosa ATCC 15442. Each microbe should be tested three times. Each test should be conducted against a separate batch of product for a total of three batches. Each of the three tests should be conducted on a different day.

Disinfectants for Use as Tuberculocides: Disinfectants may bear additional label claims of effectiveness as tuberculocides when supported by appropriate tuberculocidal effectiveness data. When using the existing or modified AOAC Tuberculocidal Activity Test Methods, 10 carriers for each of 2 samples, representing 2 different product lots at the LCL, must be tested against Mycobacterium bovis BCG (a member of the Mycobacterium tuberculosis species complex). Killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of 2 additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products) may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples at LCL representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate

in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 104 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides - Use of a Surrogate Virus: For certain viruses, there are no in vitro systems or in vivo animal models (except for humans and chimpanzees). The Agency permits the testing of surrogate viruses in these cases, for example, Bovine Viral Diarrhea virus as a surrogate for human Hepatitis C virus, Duck Hepatitis B virus as a surrogate for Human Hepatitis B virus, and Murine Norovirus/Feline Calicivirus as a surrogate for Norwalk virus.

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots at the LCL against Staphylococcus aureus (ATCC 6538) and either Klebsiella pneumoniae (aberrant, ATCC 4352) or Enterobacter aerogenes (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5×10^5 colony forming units per carrier. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Spot Soft Surface Sanitization: This study is designed to evaluate the antimicrobial efficacy of spray application sanitizers on pre-cleaned or lightly soiled, non-food contact soft surfaces. For sanitizer products intended for use on soft, non-food contact surfaces, a fabric carrier method is used to generate efficacy data. The test system proposed is a modification of the ASTM approved method for the evaluation of the antimicrobial efficacy of sanitizers on non-food contact surfaces. The method is modified for spray product application using 3 different batches at LCL. A film of bacterial cells, dried on fabric carriers, is exposed to the test substance for a specified contact time. After exposure, the carriers are transferred to vessel containing neutralizing subculture media and assayed for survivors. Appropriate viability and sterility of organism population and neutralization controls are performed. Carrier type claimed on the label must be consistent with the test system. The test material meets effectiveness requirements if the product kills an average of at least 99.9% (3 log reduction) of the required organism on the 5 replicate carriers. Controls must always meet the stipulated criteria.

Surface Sanitization of Fabrics and Textiles: For efficacy testing of antimicrobial products that bear claims of sanitization to the surface of fabrics and textiles. The Agency recommends the use of The American Society for Testing and Materials (ASTM) Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (ASTM E1153). Three product samples, representing three different batches, one of which should be at least 60 days old, should be tested against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048). The ASTM method states "an average of at least 7.5×10^5 organisms must have survived the inoculated control squares for the test to be valid." Two different fabric types should be tested. The fabrics should represent natural fabrics, such as cotton, and synthetic fabrics, such as polyester or rayon. **Evaluation of sanitizing success.** The results should demonstrate a reduction of ≥99.9 percent (a 3-$\log_{10}$ reduction) in the number of each test microorganisms over the scrubbed control count within 5 minutes.

Hard Surface Mildew Fungistatic Test: This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test

method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 day intervals of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth. Observations are made weekly for four weeks or until treatments fail and abundant growth occurs on all treated strips (at 7, 14, or 21 days). Where no growth is visually evident at the end of the test period, examination at approximately 15X magnification must be conducted to confirm the absence or establish the presence of subvisual growth. The acceptance criterion requires that all ten treated replicates per batch must be free of fungal growth. The directions for use must specify retreatment every 7, 14, or 21 days, as necessary depending on the length of time that all of the test carriers remain free of mildew growth. Labeling of products which do not permit growth after four weeks of incubation must specify a retreatment schedule, such as "repeat as necessary when new growth appears", and should indicate that treatments should be effective for at least 28 days.

Fabric Mildew Fungistatic Test Method: The test is to be conducted on cotton muslin strips cut 25 by 75 mm from 136 to 203 g/m^2 (4 to 6 oz./yd.2) fabric. The strips should be autoclaved sterilized. The product is to be tested against *Aspergillus brasiliensis* (ATCC 6275) and *Penicillium variabile* (ATCC 32333). Soak fabric strips in Nutrient broth for three minutes or until saturated. Remove excess liquid and allow fabric strips to dry before proceeding with application of the test product. Both sides of ten strips for each batch should be spray treated. The application specifications including spray distance from nozzle, degree of wetness, draining conditions, and drying procedures should be reported. Equal volumes of well-agitated conidial suspensions of Aspergillus niger and Penicillium variable using a DeVilbiss atomizer (or equivalent) should be sprayed on both sides of each fabric strip. The fabric samples are suspended in individual 500 mL jars containing 90 mL water and incubated at approximately 28°C with the caps tightened and backed off 1/8 turn to allow for ventilation. Observations are made weekly for four weeks or until treatments fail and abundant growth occurs on all treated strips (at 7, 14, or 21 days). Where no growth is visually evident at the end of the test period, examination at approximately 15X magnification must be conducted to confirm the absence or establish the presence of subvisual growth. The untreated control strips (10 strips) must have a minimum of 50% of their surface area covered with fungal growth after 7 days to consider the test valid. The acceptance criterion requires that all ten treated replicates per batch must be free of fungal growth. The directions for use must specify retreatment every 7, 14, or 21 days, as necessary depending on the length of time that all of the test strips remain free of mildew growth. Labeling of products which do not permit growth after four weeks of incubation must specify a retreatment schedule, such as "repeat as necessary when new growth appears", and should indicate that treatments should be effective for at least 28 days.

IV. DESCRIPTION OF THE EFFICACY DATA

1. MRID 501189-15, "GLP AOAC Germicidal Spray Products Test. Organisms: *Staphylococcus aureus* (ATCC 6538)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - December 14,2016. Project No. GLP1573.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (160810-001, 160810-002, and 160512-001) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1689 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 32-35 minutes. Carrier were sprayed with 6 sprays of the test substance at a distance of approximately 6 inches at ~45° angle. After the 60-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of

neutralizer/subculture medium (Letheen Broth + 0.5% Lecithin + 2.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 46 hours and 02 minutes to 46 hours and 30 minutes. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: The applicant provided the data for one failed trials. In that trial, a contaminant microorganism was observed in the test microorganism culture purity and viability controls. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. See Appendix on page 36 of the laboratory report.

2. MRID 501189-16, "AOAC Germicidal Spray Method. Organisms: *Pseudomonas aeruginosa* (ATCC 15442)" for Firebird F-130; by Jamie Herzan. Study conducted at Accuratus Lab Services; Completion date - July 5, 2016. Project No. A20096.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot 150409-001, Lot 150611-001 and Lot 150611-002) of the product, Firebird F-130, were tested using Accuratus Lab Services protocol no. SRC90122215.GS.1 (copy provided). All three product lots tested were at the LCL. The product was received ready-to-use spray. The product was received ready-to-use trigger spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism then dried at 36.1-36.6°C for 30-40 minutes and 50.2-53.5% relative humidity (RH). Carrier were sprayed with 6 sprays of the test substance at a distance of approximately 6-8 inches. After the 30-second. and 55-second exposure periods at room temperature (20-21°C) and 19% relative humidity), the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80) using sterile forceps. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol amendment was reviewed.

3. MRID 501189-1, "AOAC Germicidal Spray Method. Organisms: *Salmonella enterica* (ATCC 10708)" for Firebird F-130; by Jamie Herzan. Study conducted at Accuratus Lab Services; Completion date - April 20, 2016. Project No. A20094.

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Lot 150409-001, Lot 150611-001 and Lot 150611-002) of the product, Firebird F-130, were tested using Accuratus Lab Services protocol no. SRC90122215.GS.3 (copy provided). All three product lots tested were at the LCL. The product was received ready-to-use spray. The product was received ready-to-use trigger spray. Testing was conducted in the presence of 5% soil load. Sixty (60) glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism then dried at 36.3-36.6°C for 40 minutes and 52.4% relative humidity (RH). Carrier were sprayed with 6 sprays of the test substance at a distance of approximately 6-8 inches. After the 30-second exposure period at room temperature (19°C) and 19% relative humidity), the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80) using sterile forceps. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

4. MRID 501189-18, "GLP AOAC Germicidal Spray Products Test. Organisms: *Acinetobacter baumannii* (MDR) (ATCC BAA-1605)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - November 7,2016. Project No. GLP1479.

This study was conducted against *Acinetobacter baumannii* (MDR) (ATCC BAA-1605). Two lots (160512-001 and 160415-003) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1562

(copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Sixty (60) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 31 minutes. Carrier were sprayed with 6 sprays of the test substance at a distance of approximately 6-8 inches at ~45° angle. After the 60-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 46 hours and 02 minutes to 46 hours and 30 minutes. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Notes: Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. It is found to be resistant to Ceftadizime, Gentamicin, Ticarcillin, Piperacillin, Cefepime, Ciprofloxacin, Imipenem, and Meropenem.

5. MRID 501189-19, "GLP AOAC Germicidal Spray Products Test. Organisms: *Enterobacter aerogenes* (ATCC 13048)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - October 05,2016. Project No. GLP1434.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (160415-002 and 160415-003) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1492 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 39 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6-8 inches at ~45° angle. After the 60-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 28-32°C for 46 hours and 10 minutes. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

6. MRID 501189-20, "GLP AOAC Germicidal Spray Products Test. Organisms: *Enterococcus faecalis* (VRE) (ATCC 51575)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - December 14,2016. Project No. GLP1582.

This study was conducted against *Enterococcus faecalis* (VRE) (ATCC 51575). Two lots (160810-001 and 160810-002) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1603 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 35-45 minutes. Carrier were sprayed with 6-7 sprays (on mist setting) of the test substance at a distance of approximately 6 inches at ~45° angle. After the 60-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.5% Lecithin + 2.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 46-47 hours. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol amendment was reviewed.

Note: Antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 25923) as a control organism. A Vancomycin disk was placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. The measurement confirmed antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) to Vancomycin. See page 20 of the laboratory report.

7. MRID 501189-21, "GLP AOAC Germicidal Spray Products Test. Organisms: *Escherichia coli* (ESBL) (ATCC BAA-196)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - November 07,2016. Project No. GLP1478.

This study was conducted against *Escherichia coli* (ESBL) (ATCC BAA-196). Two lots (160512-001 and 160415-005) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1563 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 30 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6-8 inches at ~45° angle. After the 55-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.14% Lecithin +12.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 47 hours and 08 minutes. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Antibiotic resistance of Extended-Spectrum beta-lactamase (ESBL) producing *Escherichia coli* (ATCC BAA-196) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Escherichia coli* (ATCC 25922) as a control organism. Antibiotic disks were placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. *Escherichia coli* (ESBL) (ATCC BAA-196) was susceptible to Ceftadizime-clavulanate and Cefotaxime-clavulanate, but resistant to Ceftadizime and Cefotaxime. See page 18 of the laboratory report.

8. MRID 501189-22, "GLP AOAC Germicidal Spray Products Test. Organisms: *Escherichia coli* (O157:H7) (ATCC 35150)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - November 07,2016. Project No. GLP1477.

This study was conducted against *Escherichia coli* (O157:H7) (ATCC 35150). Two lots (160512-001 and 160415-005) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1493 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 30 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6-8 inches at ~45° angle. After the 55-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.14% Lecithin +12.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 46 hours. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol amendments were reviewed.

9. MRID 501189-23, "GLP AOAC Germicidal Spray Products Test. Organisms: *Klebsiella pneumoniae* (CRE) (ATCC BAA-2146)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - November 07,2016. Project No. GLP1476.

This study was conducted against *Klebsiella pneumoniae* (CRE) (ATCC BAA-2146). Two lots (160512-001 and 160415-005) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1564 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 27-36 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6-8 inches at ~45° angle. After the 55-60 seconds exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.14% Lecithin +12.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 46 hours and 02-55 seconds. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol amendments and deviation were reviewed.

Note: Antibiotic resistance of *Klebsiella pneumoniae* (CRE) (ATCC BAA-2146) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using Pseudomonas aeruginosa (ATCC 27853) as a control organism. Antibiotic disks were placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. The measurement confirmed antibiotic resistance of *Klebsiella pneumoniae* (CRE) (ATCC BAA-2146) to resistant to Imipenem and Meropenem. See page 19 of the laboratory report.

10. MRID 501189-24, "GLP AOAC Germicidal Spray Products Test. Organisms: *Staphylococcus aureus* (MRSA) (ATCC 33592)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - December 14,2016. Project No. GLP1583.

This study was conducted against *Staphylococcus aureus* (MRSA) (ATCC 33592). Two lots (160810-001 and 160810-002) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1604 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 31 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6 inches at ~45° angle. After the 60-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.5% Lecithin + 2.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 47 hours. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviation was reviewed.

Note: Antibiotic resistance of *Staphylococcus aureus* (MRSA) (ATCC 33592) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 25923) as a control organism. A Vancomycin disk was placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. The measurement confirmed antibiotic resistance of *Staphylococcus aureus* (MRSA) (ATCC 33592) to Cefoxitin (Methicillin). See page 18 of the laboratory report.

11. MRID 501189-25, "GLP AOAC Germicidal Spray Products Test. Organisms: *Staphylococcus epidermidis* (MRSE) (ATCC 51625)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - December 19, 2016. Project No. GLP1598.

This study was conducted against *Staphylococcus epidermidis* (MRSE) (ATCC 51625). Two lots (161005-001 and 160810-002)) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1603 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 30 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6 inches at ~45° angle. After the 60-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.5% Lecithin + 2.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 46 hours and 04 minutes. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Antibiotic resistance of *Staphylococcus epidermidis* (MRSE) (ATCC 51625) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using *Staphylococcus aureus* (ATCC 25923) as a control organism. A Vancomycin disk was placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. The measurement confirmed antibiotic resistance of *Staphylococcus epidermidis* (MRSE) (ATCC 51625) to Cefoxitin (Methicillin). See page 18 of the laboratory report.

12. MRID 501189-26, "GLP AOAC Germicidal Spray Products Test. Organisms: *Staphylococcus aureus* (VRSA) (HIP11714)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - December 14, 2016. Project No. GLP1599.

This study was conducted against *Staphylococcus aureus* (VRSA) (HIP11714). Two lots (161005-001 and 160810-002)) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1606 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 35 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6 inches at ~45° angle. After the 60-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.5% Lecithin + 2.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 47 hours and 46 minutes. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Antimicrobial Susceptibility Testing was conducted on representative cultures of the microorganisms using MIC method, against Vancomycin. *Staphylococcus aureus* (VRSA) (HIP11714) was found to be Resistant to Vancomycin. See "Attachment I" on pages 18 of the laboratory report.

13. MRID 501189-27, "GLP AOAC Germicidal Spray Products Test. Organisms: *Staphylococcus aureus* (VISA) (HIP5836)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - December 14, 2016. Project No. GLP1600.

This study was conducted against *Staphylococcus aureus* (VISA) (HIP5836). Two lots (161005-001 and 160810-002)) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1607 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 35 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6 inches at ~45° angle. After the 60-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.5% Lecithin + 2.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 47 hours and 46 minutes. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Antimicrobial Susceptibility Testing was conducted on representative cultures of the microorganisms using MIC method, against Vancomycin. *Staphylococcus aureus* (VISA) (HIP5836) was found to have Intermediate Resistance to Vancomycin. See "Attachment I" on pages 18 of the laboratory report.

14. MRID 501189-28, "GLP AOAC Germicidal Spray Products Test. Organisms: *Pseudomonas aeruginosa* MBL (CDC AR-0246/PSA-18)" for Firebird F-130; by Nicholas Garcia. Study conducted at Microchem Laboratory; Completion date - November 10, 2016. Project No. GLP1558.

This study was conducted against *Pseudomonas aeruginosa* MBL (CDC AR-0246/PSA-18). Two lots (160810-001 and 160810-002) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1672 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48-54 hours old culture of the test organism. Carriers were dried at 35-37°C for 26 minutes. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6-8 inches at ~45° angle. After the 55-second exposure period at room temperature, the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.14% Lecithin + 1.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 35-37°C for 46 hours and 16 minutes. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviation was reviewed.

Note: Antibiotic resistance of *Pseudomonas aeruginosa* MBL (CDC AR-0246/PSA-18) was verified on a representative culture. An individual Mueller Hinton agar plate was streaked with the prepared culture. A control agar was prepared using Pseudomonas aeruginosa (ATCC 27853) as a control organism. Antibiotic disks were placed on each plate. The plates were incubated and, following incubation, the zone of inhibition was measured. The measurement confirmed antibiotic resistance of *Pseudomonas aeruginosa* MBL (CDC AR-0246/PSA-18) to resistant to Imipenem and Imipenem + EDTA. See page 18 of the laboratory report.

15. MRID 501189-29, "Fungicidal Germicidal Spray Method. Organism: *Trichophyton mentagrophytes* (ATCC 9533)" for Firebird F-130; by Maggie Brusky. Study conducted at Accuratus Lab Services; Study completion date - October 19, 2016. Project No. A21241.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two batches (Lot 150611-001 and Lot 150611-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90052416.FGS (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten glass carriers per

product batch were inoculated with 10.0 µL of conidia preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 35 minutes at 36.5°C and 52.4% relative humidity, and were used within 2 hours of drying. Carrier were sprayed with 3 sprays of the test substance at a distance of approximately 6-8 inches. The carriers were exposed for 3 minutes at 19.2°C and 69% relative humidity. Following exposure, individual carriers were drained and transferred to 20 mL Sabouraud Dextrose Broth+ 0.07% Lecithin + 0.5% Tween 80. All neutralized subcultures were incubated 10 days at 25-30°C, and the agar plate subcultures were incubated for 66-76 hours at 25-30°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

16. MRID 501189-30, "Fungicidal Germicidal Spray Method. Organism: *Aspergillus niger* (ATCC 6275)" for Firebird F-130; by Maggie Brusky. Study conducted at Accuratus Lab Services; Study completion date - October 24, 2016. Project No. A21500.

This study was conducted against *Aspergillus niger* (ATCC 6275). Two batches (Lot 160415-002 and Lot 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.FGS.2 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten glass carriers per product batch were inoculated with 10.0 µL of conidia preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 31 minutes at 36.6-36.8°C and 54.7% relative humidity, and were used within 2 hours of drying. Carrier were sprayed with 3 sprays of the test substance at a distance of approximately 6-8 inches. The carriers were exposed for 3 minutes at 20°C and 47% relative humidity. Following exposure, individual carriers were drained and transferred to 20 mL Sabouraud Dextrose Broth+ 0.07% Lecithin + 0.5% Tween 80. All neutralized subcultures were incubated for 10 days at 25-30°C. Subcultures were stored at 2-8°C for two days prior to examination (see Protocol Deviation). The agar plate subcultures were incubated for 44-52 hours at 25-30°C. The agar plate subcultures were stored at 2-8°C for two days prior to examination. Following incubation and storage, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviation was reviewed.

17. MRID 501189-31, "GLP AOAC Germicidal Spray Products Test. Organism: *Candida albicans* (ATCC 10231)" for Firebird F-130; by Nicholas Garcia. Study conducted at Accuratus Lab Services; Study completion date - December 14, 2016. Project No. GLP1596.

This study was conducted against *Candida albicans* (ATCC 10231). Two batches (161005-001 and 160810-002) of the product, Firebird F-130, were tested using Microchem Laboratory protocol no. P1608 (copy provided). All product lots tested were at the LCL. The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Ten glass carriers per product batch were inoculated with 10.0 µL of culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 34 minutes at 36.6-36.8°C and 54.7% relative humidity, and were used within 2 hours of drying. Carrier were sprayed with 6 sprays (on mist setting) of the test substance at a distance of approximately 6-8 inches at ~45° angle. The carriers were exposed for 60 seconds at room temperature. Following exposure, individual carriers were drained and transferred to 20 mL Sabouraud Dextrose Broth+ 0.5% Lecithin + 2.0% Tween 80. All neutralized subcultures were incubated for 46 hours and 05 minutes at 28-32°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviations were reviewed.

18. MRID 501189-32, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus" for Firebird F-130; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 30, 2016. Project Number A 20898.

This study was conducted against 11/4/12 Strain of Duck Hepatitis B virus (DHBV; Hepadnavirus Testing Inc., Palo Alto, CA) as a surrogate virus for human Hepatitis B virus, using primary duck hepatocytes (PDH; Abendroth Hatchery by Valley Research Institute (VRI)) as the host system. Two lots (Lot Nos. 160415-002 and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.DHBV (copy provided). The product was received ready-to-use spray. The stock virus culture contains 100% whole duck serum. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 21.0°C for 30 minutes at 38.4% relative humidity. For each lot of product, two dried virus films were sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were exposed for 10 seconds at 21.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Leibovitz L-15 medium supplemented with 0.1 % glucose, 10 µM dexamethasone, 10 µg/ml insulin, 20 mM HEPES, 10 µg/ml gentamicin, and 100 units/ml penicillin. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 0.25 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 9 days for cytotoxicity and the cells were fixed with ethanol. An indirect immunofluorescence assay was then performed using a monoclonal antibody specific for the envelope protein of the DHBV. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.5 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.0 $\log_{10}$** for both batches.

19. MRID 501189-33, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus" for Firebird F-130; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 29, 2016. Project Number A 20925.

This study was conducted against the Oregon C24v-genotype 1 strain of Bovine Viral Diarrhea virus (BVDV; National Veterinary Services Laboratories (NVSL), Ames, IA.), using BT (Bovine Turbinate) cells (ATCC CRL-1390) as the host system. Two lots (Lot Nos. 160415-002 and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.BVD (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (horse serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of product, two dried virus films were sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 seconds at 21.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% (v/v) non-heat inactivated horse serum, 10 µg/ml gentamicin, 100 units/ml penicillin and 2.5 µg/ml amphotericin B. BT cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. The determination of CPE can be subjective, therefore to verify the CPE reading, on the final day of incubation a direct immunofluorescence assay (DFA) which is a more sensitive detection method to detect the virus in the host cells was performed using a polyclonal fluorescein conjugated antibody specific for BVDV, received from VMRD, Inc., Pullman, WA. The DFA was performed only on the first inoculated dilution of the test (10^{-1} dilution) and the 10^{-4} and 10^{-5} dilutions of the dried virus control. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.25 $\log_{10}$**. Taking the

cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.75 log_{10}** for both batches.

20. MRID 501189-34, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Herpes simplex virus type 1" for Firebird F-130; by Shanen Conway. Study conducted at Accuratus Lab Services. Study completion date – July 12, 2016. Project Number A 21016.

This study was conducted against Herpes simplex virus type 1, Strain F(1) (ATCC VR-733), using Vero cells (ATCC CCL-81) as the host system. Two lots (Lot Nos. 160415-002 and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.HSV1 (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 seconds at 21.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **4.5 log_{10}**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.0 log_{10}** for both batches.

21. MRID 501189-35, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Herpes simplex virus type 2" for Firebird F-130; by Shanen Conway. Study conducted at Accuratus Lab Services. Study completion date – July 12, 2016. Project Number A 21015.

This study was conducted against Herpes simplex virus type 2, Strain G (ATCC VR-734), using Vero cells (ATCC CCL-81) as the host system. Two lots (Lot Nos. 160415-002 and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.HSV2 (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 seconds at 21.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.25 log_{10}**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **3.75 log_{10}** for both batches.

22. MRID 501189-36, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Human Coronavirus" for Firebird F-130; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 30, 2016. Project Number A 20995.

This study was conducted against Human Coronavirus, Strain 229E (ATCC VR-740), using WI-38 (human lung) cells (ATCC CCL-75) as the host system. Two lots (Lot Nos. 160415-002 and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.COR (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 seconds at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 2% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. WI-38 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 10 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.50 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **5.00 $\log_{10}$** for both batches.

23. MRID 501189-37, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Human Immunodeficiency Virus type 1" for Firebird F-130; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – October 10, 2016. Project Number A 21002.

This study was conducted against Human Immunodeficiency Virus type 1, Strain HTLV-III_B (obtained from Advanced Biotechnologies, Inc., Columbia, MD), using MT-2 cells {human T-cell leukemia cells; obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH) as the host system. Two lots (Lot Nos. 160415-002 and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.HIV (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 19.0°C for 20 minutes at 54.7% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 seconds at 19.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in RPMI-1640 supplemented with 15% (v/v) heat-inactivated fetal bovine serum (FBS), 2.0 mM L-glutamine and 50 µg/mL gentamicin. MT-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 14 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.5 $\log_{10}$** for both batches.

24. MRID 501189-38, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Avian Influenza A (H3N2) Reassortant virus" for Firebird F-130; by Mary J. Miller. Study

conducted at Accuratus Lab Services. Study completion date – July 1, 2016. Project Number A20567.

This study was conducted against Avian Influenza A (H3N2) Reassortant virus, (ATCC VR-2072), Strain A/Washington/897/80 x NMallard/New York/6750/78, using MDCK cells (canine kidney, ATCC CCL-34) as the host system. Two lots (Lot Nos. 150611-001 and 150611-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.AFLU (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50.0% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 seconds at 21.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 2 µg/ml TPCK-trypsin, 25 mM HEPES, 0.2% bovine serum albumin (BSA) fraction V, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **4.50 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.00 $\log_{10}$** for both batches.

25. MRID 501189-39, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: 2009-H1 N1 Influenza A virus (Novel H1 N1)" for Firebird F-130; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 30, 2016. Project Number A20994.

This study was conducted against 2009-H1N1 Influenza A virus (Novel H1N1) Strain A/Mexico/4108/2009, (CDC #2009712192), using MDCK cells (canine kidney, ATCC CCL-34) as the host system. Two lots (Lot Nos. 160415-002 and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.FLUA (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 32.1% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 seconds at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 2 µg/ml TPCK-trypsin, 25 mM HEPES, 0.2% bovine serum albumin (BSA) fraction V, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.75 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **6.25 $\log_{10}$** for both batches.

26. MRID 501189-40, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus" for Firebird F-130; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – July 1, 2016. Project Number A20534.

This study was conducted against F-9 strain of Feline Calicivirus (ATCC VR-782), using CRFK cells (Crandel Reese feline kidney cells, ATCC CCL-94) as the host system. Two lots (Lot Nos. 150611-001 and 150611-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.FCAL (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50.0% relative humidity. For each lot of product, two dried virus films were sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 21.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin and 2.5 µg/ml amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.25 log_{10}**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **5.75 log_{10}** for both batches.

27. MRID 501189-41, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Poliovirus type 1" for Firebird F-130; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – December 21, 2016. Project Number A21684.

This study was conducted against Poliovirus type 1, Strain Chat (ATCC VR-1562), using Vero cells (ATCC CCL-81) as the host system. Two lots (Lot Nos. 160810-001 and 160810-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90082316.POL (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 15.5°C for 20 minutes at 55% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 and 6 sprays). The virus films were completely covered with the use solution, and remained exposed to the use solution for 3 minutes and 4 minutes 45 seconds at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **4.75 log_{10}** and **5.5 log_{10}.** Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **3.25 log_{10}** and **4.00** for the batches.

Note: Protocol amendments were reviewed.

Note: The applicant provided the data for two failed trials. In those trials, the numbers controls were below the required number 4 log_{10}. Thus, the tests were invalid. These data were not used to evaluate efficacy of the test product. See Attachments I and II on pages 27 and 29 of the laboratory report

28. MRID 501189-41, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Respiratory syncytial virus (RSV)" for Firebird F-130; by Shanen Conway. Study

conducted at Accuratus Lab Services. Study completion date – August 26, 2016. Project Number A21001.

This study was conducted against Respiratory syncytial virus (RSV), Strain Long (ATCC VR-26), using Hep-2 cells (human larynx carcinoma, ATCC CCL-23) as the host system. Two lots (Lot Nos. 160415-002 and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.RSV (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 50% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays each). The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 seconds at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat-inactivated fetal bovine serum (FBS), 10 µg/ml gentamicin, 100 units/ml penicillin, 1.0 mM L-glutamine and 2.5 µg/ml amphotericin B. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 9 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **4.75 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.25 $\log_{10}$** for both batches.

29. MRID 501189-43, "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Rotavirus" for Firebird F-130; by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – October 11, 2016. Project Number A21683.

This study was conducted against Rotavirus, Strain WA (ATCC VR-2018), using MA-104 cells ((Rhesus monkey kidney, ATCC CCL-2378.1) as the host system. Two lots (Lot Nos. 160810-001 and 160810-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90082316.ROT.1 (copy provided). The product was received ready-to-use spray. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of product, one dried virus film was sprayed at a distance of 6-8 inches until the carrier surfaces were visibly wet (3 sprays). The virus films were completely covered with the use solution, and remained exposed to the use solution for 2 minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium (MEM) supplemented with 10 µg/ml gentamicin, 100 units/ml penicillin, 2.5 µg/ml amphotericin B, 0.5 µg/ml trypsin and 2.0 mM L-glutamine. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.75 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **4.25** for both batches.

30. MRID 501189-44, "AOAC Tuberculocidal Activity of Disinfectant Spray Products. Organism: *Mycobacterium bovis* - BCG" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - July 06, 2016. Project No. A19362.

This study was conducted against *Mycobacterium bovis* - BCG. Two batches (Lot 150611-001 and Lot 150409-001) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.TB.1 (copy provided). All product lots tested were at the LCL. The product was received ready-

to-use spray. Testing was conducted in the presence of 5% soil load. Ten glass carriers per product batch were inoculated with 10.0 µL of standardized 20-days culture preparation, spread over approximately 1 square inch of the slide. Carriers were dried for 30 minutes at 36.6-36.7°C and 50.8% relative humidity, and were used within 2 hours of drying. Carrier were sprayed with 3 sprays of the test substance at a distance of approximately 6-8 inches. The carriers were exposed for 3 minutes at 20.1°C and 21.6% relative humidity. Following exposure, individual carriers were drained and transferred to 20 mL Horse Serum + 0.5% Tween 80. The vessel containing the carrier in neutralizer was shaken and the carrier was transferred to a vessel containing 20 ml of Modified Proskauer-Beck Broth. Within approximately 30 minutes of neutralization, a 2.0 ml aliquot of the neutralizer was transferred to individual vessels containing 20 ml of Middlebrook 7H9 Broth and 20 ml of Kirchner's Medium. Each subculture vessel was shaken thoroughly. All subculture broths were incubated at 35-37°C under aerobic conditions. The subcultures were visually examined for growth following a 30 and 62 days incubation period. All test subcultures demonstrated a lack of growth of the test organism therefore the subcultures were incubated an additional 30 days and re-examined. Controls included purity, sterility, viability, neutralization confirmation, and carrier population.

Note: Protocol deviations and amendments were reviewed.

Note: The applicant provided the data for one failed trial. In the trial, the Neutralization Confirmation Control failed. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. See Attachments I on pages 18 of the laboratory report

31. MRID 501189-45, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organisms: *Enterobacter aerogenes* (ATCC 13048), *Pseudomonas aeruginosa* (ATCC 15442), and *Staphylococcus aureus* (ATCC 6538)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - May 24, 2016. Project No. A19382.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048), *Pseudomonas aeruginosa* (ATCC 15442), and *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 150409-001, 150611-001 and 150611-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90092115.CUST.1.PROP, EPA Protocol 42182-PA-3 (copy provided). The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per organism per product lot were treated (3 sprays with the product from a distance of 6-8 inches at 45° angle) and allowed to dry uncovered at 21.0 - 22.0°C, 45-48% relative humidity in a humidity controlled chamber for 30 minutes, or until visually dry up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 35.1-36.1°C for 30-35 minutes, or until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (19.9-20.7°C) and room humidity (25.0-44.4%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 21.0°C and 45-48% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes, the carriers were transferred to 10 ml of Letheen Broth+ 0.28% Lecithin+ 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48-54 hours at 30±2°C for *Enterobacter aerogenes* and at 35±2°C for *Staphylococcus aureus* and *Pseudomonas aeruginosa*. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, putity, and neutralization.

32. MRID 501189-46, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organism: Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - May 11, 2016. Project No. A19778.

This study was conducted against Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575). Two lots (Lot Nos. 150611-001 and 150611-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90092115.CUST.3.PROP (copy provided). The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per organism per product lot were treated (3 sprays with the product from a distance of 6-8 inches at 45° angle) and allowed to dry uncovered at 21.0°C, 47% relative humidity in a humidity controlled chamber for 30 minutes, or until visually dry up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.7°C for 30-35 minutes, or until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (20°C) and room humidity (29-30%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 21.0°C and 45-48% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0 g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes, the carriers were transferred to 10 ml of Letheen Broth+ 0.28% Lecithin+ 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48-54 hours at 35±2°C. Day 2 subcultures were placed at 2-8°C for 1 day prior to examination. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, putity, and neutralization.

Note: Antibiotic resistance of Enterococcus faecalis - VRE was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. Staphylococcus aureus (ATCC 25923) was the control organism. The measured zone of inhibition confirmed antibiotic resistance of Enterococcus faecalis - VRE to vancomycin. See Table7, page 21, of the laboratory report.

33. MRID 501189-47, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organism: Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - May 12, 2016. Project No. A19779.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592). Two lots (Lot Nos. 150611-001 and 150611-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90092115.CUST.2.PROP (copy provided). The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per organism per product lot were treated (3 sprays with the product from a distance of 6-8 inches at 45° angle) and allowed to dry uncovered at 21.0°C, 47% relative humidity in a humidity controlled chamber for 30 minutes, or until visually dry up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.7°C for 30-35 minutes, or until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (20°C) and room humidity (31-35%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 21.0°C and 45% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0g. The abrasion tester was set to a speed of 2.25-2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion

cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes, the carriers were transferred to 10 ml of Letheen Broth+ 0.28% Lecithin+ 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48-54 hours at 35±2°C. Day 2 subcultures were placed at 2-8°C for 2 days prior to examination. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, putity, and neutralization.

Note: Antibiotic resistance of ***Staphylococcus aureus* - MRSA** was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition confirmed antibiotic resistance of *Staphylococcus aureus* - MRSA to oxacillin. See Table7, page 21, of the laboratory report.

34. MRID 501189-48, "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application). Organism: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538)" for Firebird F-130; by Maggie Brusky. Study conducted at Accuratus Lab Services; Study completion date - October 19, 2016. Project No. A21548.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (160810-001, 160810-002, and 160415-003) of the product, Firebird F-130, were tested according to Accuratus Lab Services protocol no. SRC90081115.NFS.1 (copy provided). The product was received ready-to-use trigger spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Five (5) glass carriers (1 inch x 1 inch) per product lot were inoculated with 0.02 mL of a 48-54 hour culture/soil suspension of the test organism. The carriers were dried for 20 minutes at 36.0-36.1°C and 40% relative humidity with the Petri dish lids slightly ajar. Carriers were sprayed at a distance of 6-8 inches using 3 sprays until uniformly wet and were allowed to expose at room temperature (20°C) and 45% relative humidity for 10 seconds. Following exposure, each carrier was transferred to 20 mL of D/E Neutralizing Broth; the excess liquid in each Petri dish was transferred to the neutralizer jar containing the matching carrier. The carriers were vortex-mixed for 10-15 seconds to ensure complete elution of the test organism. Within 30 minutes of neutralization, duplicate 1.0 ml and 0.1 ml aliquots of the neutralized solution (10^0) were plated onto Tryptic Soy Agar with 5% Sheep Blood. The culture/control medium plates were incubated at 35-37°C for 48±4 hours for S. *aureus* and 25-32°C for 48±4 hours for *E. aerogenes*. The subcultures were placed at 2-8°C for 3 days prior to examination. Following incubation and storage, the subcultures were visually enumerated. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

35. MRID 501189-49, "Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application). Organism: *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538)" for Firebird F-130; by Maggie Brusky. Study conducted at Accuratus Lab Services; Study completion date - October 06, 2016. Project No. A21260.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (160415-002, 160415-003, and 160512-001) of the product, Firebird F-130, were tested according to Accuratus Lab Services protocol no. SRC90092115.NFS (copy provided). The product was received ready-to-use trigger spray. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Five (5) cotton and five (5) polyester carriers (1 inch x 1 inch) per product lot were inoculated with 0.03 mL of a 48-54 hour culture/soil suspension of the test organism. The carriers were dried for 23-26 minutes at 36.0-36.2°C and 40% relative humidity with the Petri dish lids intact. Carriers were sprayed at a distance of 6-8 inches using 3 sprays until uniformly wet and were allowed to expose at room temperature (20°C) and 53-55% relative humidity for 10 seconds. Following exposure, each carrier was transferred to 20 mL of D/E Neutralizing Broth; the excess liquid in each Petri dish was transferred to the neutralizer jar containing the matching carrier. The

carriers were vortex-mixed for 10-15 seconds to ensure complete elution of the test organism. Within 30 minutes of neutralization, duplicate 1.0 ml and 0.1 ml aliquots of the neutralized solution (10^0) were plated onto Tryptic Soy Agar with 5% Sheep Blood (SAP). The culture/control medium plates were incubated at 35-37°C for 48±4 hours for S. *aureus* and 25-32°C for 48±4 hours for *E. aerogenes*. The subcultures were placed at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were visually enumerated. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

36. MRID 501189-50, "EPA Hard Surface Mildew-Fungistatic Test. Organism: *Aspergillus niger* (ATCC 6275)" for Firebird F-130; by Jamie Herzan. Study conducted at Accuratus Lab Services; Study completion date - June 29, 2016. Project No. A20568.

This study was conducted against *Aspergillus niger* (ATCC 6275). Two lots (Lot Nos. 150611-001 and 150611-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.MSTAT (copy provided). The product was received ready-to-use spray. A conidial suspension of a 10 days old culture containing 5% fetal bovine serum was used. Sterile 1 x 1" glazed ceramic tiles (10 per treatment) were sprayed with 3 sprays of the test substance at a distance of approximately 6-8 inches. Then, excess liquid was allowed to drain off and the tiles were dried for 21 minutes at 35-37°C. Untreated glazed tiles were also held for 21 minutes at 35-37°C. Following the drying period, the surfaces of each test tile and each control tile were sprayed (2X) with the conidial suspension using a DeVilbiss #152 atomizer. The tiles were returned to 35-37°C and dried for 48 minutes. Each tile (treated side up) was placed onto an individual water agar plate. All plates were incubated for 7 days at 25-30°C in a minimum of 95% relative humidity. When no growth was visually observed, a magnified examination was performed. Controls included those for purity and sterility. The reported growth percentages on **untreated control tiles range from 70% to 100%**.

37. MRID 501189-51, "Fabric Mildew Fungistatic Test. Organisms: *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - June 07, 2016. Project No. A20284.

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333). Two lots (Lot Nos. 150409-001 and 150611-001) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90081115.FMSTAT [as published in EPA's Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 1: Fabric Mildew Fungistatic Test Method, November 1982)] (copy provided). The product was received ready-to-use. The fungi were inoculated from stock cultures onto agar plates and incubated at 25-30°C for eight and ten days. Upon maturity, the spores were removed, and the suspensions were filtered through sterile cotton to remove the hyphae and hyphal fragments. Strips measuring 25 x 75 mm each were cut from unbleached cotton fabric. Each strip weighed 136 to 203 g/m^2 (to conform to the EPA guidelines). All strips were autoclaved, with a subsequent soak in glycerol nutrient solution for 3 minutes. Each fabric strip was dried under sterile conditions before use. Ten dried, nutrient saturated fabric strips per lot were evaluated. Using a spray bottle, each lot of product was sprayed 3 times, from a distance of 6-8 inches, onto the fabric strips. The strips were hung in the sterile laminar air flow hood. Ten untreated fabric strips were sprayed with saline solution in place of the test agent for the untreated control. All samples were allowed to dry (room temperature (24.0°C) for 30 minutes) before inoculation. Equal volumes of 5 x 10^6 conidia/ml suspension of *A. niger* and *P. variabile* were mixed together and agitated. Each side of each fabric strips was lightly sprayed to inoculate the mixed conidial suspension using a DeVilbiss atomizer (approximately 6 sprays). The fabric samples were suspended in individual 250 ml French Square bottles containing approximately 10 ml sterile deionized water and incubated at 25-30°C. Observations were made and recorded weekly for 4 weeks (minimally 7, 14, 21 and 28 days). The presence or absence of observable mold on the fabric strips was the criterion for determining the efficacy of the test agent. When no visible growth was evident at the end of the test period, the fabric strips were examined microscopically. Controls included those for purity and sterility. The reported growth percentages on untreated control strips were 100%

V. STUDY RESULTS

MRID Number	Organism	No. Carriers Exhibiting Growth/Total			Carrier Population (log_{10})
		160810-001	160810-002	160512-001	
501189-15	*Staphylococcus aureus* (ATCC 6538)	0/60	1/60	1/60	5.61/5.64/5.66
501189-20	*Enterococcus faecalis* (VRE) (ATCC 51575)	0/10	0/10	-	4.99/4.97
501189-24	*Staphylococcus aureus* (MRSA) (ATCC 33592)	0/10	0/10	-	4.75
501189-28	*Pseudomonas aeruginosa* MBL (CDC AR-0246/PSA-18).	0/10	0/10	-	4.03
				161005-001	
501189-25	*Staphylococcus epidermidis* (MRSE) (ATCC 51625)	-	0/10	0/10	4.20
501189-26	*Staphylococcus aureus* (VRSA) (HIP11714)	-	0/10	0/10	4.92
501189-27	*Staphylococcus aureus* (VISA) (HIP5836)	-	0/10	0/10	4.68
501189-31	*Candida albicans* (ATCC 10231)	-	0/10	0/10	4.02
		150409-001	**150611-001**	**150611-002**	
501189-16	*Pseudomonas aeruginosa* (ATCC 15442)	1/60	1/60	0/60	5.82/5.59
501189-17	*Salmonella enterica* (ATCC 10708)	1/60	1/60	0/60	4.44
501189-29	*Trichophyton mentagrophytes* (ATCC 9533)	-	0/10	0/10	4.14
501189-				-	
		160512-001	**160415-002**	**160415-003**	
501189-18	*Acinetobacter baumannii* (MDR) (ATCC BAA-1605).	0/10	-	0/10	4.92
501189-19	*Enterobacter aerogenes* (ATCC 13048)	-	0/10	0/10	4.95
501189-21	*Escherichia coli* (ESBL) (ATCC BAA-196)	0/10	-	0/10	4.41
501189-22	*Escherichia coli* (O157:H7) (ATCC 35150)	0/10	-	0/10	5.06
501189-23	*Klebsiella pneumoniae* (CRE) (ATCC BAA-2146)	0/10	-	0/10	4.05/5.01
501189-30	*Aspergillus niger* (ATCC 6275)	-	0/10	0/10	5.87

MRID Number	Organism	Description	Results		Dried Virus Control
			160415-002	160415-003	
501189-32	Duck Hepatitis B Virus, Strain 11/4/12 (as a surrogate for	10^{-1} dilution	Complete Inactivation	Cytotoxic	$10^{5.50}$ ($TCID_{50}$/0.25mL)
		10^{-2} - 10^{-4} dilutions	Complete Inactivation	Complete Inactivation	

	Human Hepatitis B Virus)	$TCID_{50}$/0.25mL	$\leq 10^{0.50}$	$\leq 10^{1.50}$	
		Log Reduction	≥5.00	≥4.00	
501189-33	Bovine Viral Diarrhea Virus (as a Surrogate Virus for Human Hepatitis C Virus)	10^{-1} - 10^{-4} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.25}$ ($TCID_{50}$/0.1mL)
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.75	≥4.75	
501189-34	Herpes simplex virus type 1, Strain F(1) (ATCC VR-733)	10^{-1} - 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.50}$ ($TCID_{50}$/0.1 mL)
		$TCID_{50}$/0.1 mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.00	≥4.00	
501189-35	Herpes simplex virus type 2, Strain G (ATCC VR-734)	10^{-1} - 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.25}$ ($TCID_{50}$/0.1 mL)
		$TCID_{50}$/0.1 mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1 mL	$\leq 10^{0.50}$	$\leq 10^{1.50}$	
		Log Reduction	≥4.75	≥3.75	
501189-36	Human Coronavirus, Strain 229E (ATCC VR-740)	10^{-1} - 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.50}$ ($TCID_{50}$/0.1 mL)
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥5.00	≥5.00	
501189-37	Human Immunodeficiency Virus type 1, Strain $HTLV\text{-}III_B$	10^{-1} dilution	Cytotoxic	Cytotoxic	$10^{6.00}$ ($TCID_{50}$/0.2mL)
		10^{-2} - 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.2mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		Log Reduction	≥4.50	≥4.50	
501189-39	2009-H1N1 Influenza A virus (Novel H1N1) (CDC #2009712192)	10^{-1} - 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.75}$ ($TCID_{50}$/0.1 mL)
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥6.25	≥6.25	
501189-42	Respiratory syncytial virus (RSV), Strain Long (ATCC VR-26)	10^{-1} - 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.75}$ (TCID50/0.1 mL)
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.25	≥4.25	
			150611-001	**150611-002**	
501189-38	Avian Influenza A (H3N2) Reassortant virus, (ATCC VR-2072)	10^{-1} - 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{4.50}$ ($TCID_{50}$/0.1 mL)
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥4.00	≥4.00	
501189-40	F-9 strain of Feline Calicivirus (ATCC VR-782)	10^{-1} - 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.25}$ ($TCID_{50}$/0.1 mL)
		$TCID_{50}$/0.1mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		Log Reduction	≥5.75	≥5.75	
			160810-001	**160810-002**	
501189-41	Poliovirus type 1, Strain Chat (ATCC VR-1562)	10^{-1} dilution	Inactivation / Cytotoxic	Cytotoxic	$10^{4.75}$ / $10^{5.50}$ ($TCID_{50}$/0.1 mL)
		10^{-2} - 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.25mL	$10^{1.0}/\leq 10^{1.50}$	$\leq 10^{1.50}$	

		Log Reduction	3.75/≥4.00	≥3.25	
501189-43	Rotavirus, Strain WA (ATCC VR-2018)	10^{-1} - 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.75}$ ($TCID_{50}$/0.1mL)
		$TCID_{50}$/0.1 mL	$\leq 10^{0.50}$	$\leq 10^{0.50}$	
		TCD_{50}/0.1 mL	$\leq 10^{1.50}$	$\leq 10^{1.50}$	
		Log Reduction	≥4.25	≥4.25	

MRID # 501189-43	Lot #	Subculture Medium	Number of carrier showing growth/Exposed			Average (log_{10})
			Day 30	Day 62	Day 90	
Mycobacterium bovis - BCG	150409-001	MPB	0/10	0/10	0/10	5.49
		7H9	0/10	0/10	0/10	
		KM	0/10	0/10	0/10	
	150611-001	MPB	0/10	0/10	0/10	
		7H9	0/10	0/10	0/10	
		KM	0/10	0/10	0/10	

MRID #	Carrier Type	Lot No.	CFU/Carrier Average Log_{10}	Percent Reduction	Carrier Population (log_{10} CFU/Carrier)	
					Non-Abrasion	Abrasion
501189-45	*Enterobacter aerogenes* (ATCC 13048)	150409-001, 150611-001 150611-002	<1.00 <1.00 <1.00	>99.999% >99.999% >99.999%	6.27/6.50	6.28/6.65/
	Pseudomonas aeruginosa (ATCC 15442)	150409-001, 150611-001 150611-002	<1.40 <1.49 <1.65	99.999% >99.999% 99.999%	6.67	6.65
	Staphylococcus aureus (ATCC 6538)	150409-001, 150611-001 150611-002	<1.00 <1.00 <1.00	>99.999% >99.999% >99.999%	6.72	6.74
501189-46	Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575)	150611-001 150611-002	<1.00 <1.00	>99.999% >99.999%	6.41	6.26
501189-47	Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)	150611-001 150611-002	<1.00 <1.00	>99.999% >99.999%	6.91	7.14

MRID Number	Organism	Lot No.	CFU/Carrier Average Log_{10}	Percent Reduction	Carrier Population (Log_{10} CFU/Carrier)
501189-48	*Enterobacter aerogenes* (ATCC 13048)	160810-001 160810-002 160415-003	<2.41 <1.62 <1.52	>99.9% >99.9% >99.9%	6.45

	Staphylococcus aureus (ATCC 6538)	160810-001 160810-002 160415-003	<2.30 <2.30 <2.30	>99.9% >99.9% >99.9%	6.36

MRID # 501189-49	Carrier Type	Lot No.	CFU/Carrier Average Log_{10}	Percent Reduction	Carrier Population (Log_{10} CFU/Carrier)
Enterobacter aerogenes (ATCC 13048)	100% Plain Cotton Weave	160415-002 160415-003 160512-001	<1.30 <1.30 <1.50	>99.9% >99.9% >99.9%	6.77
	100% Polyester	160415-002 160415-003 160512-001	<1.30 <1.30 <1.30	>99.9% >99.9% >99.9%	7.20
Staphylococcus aureus (ATCC 6538)	100% Plain Cotton Weave	160415-002 160415-003 160512-001	<2.30 <2.30 <2.30	>99.9% >99.9% >99.9%	6.99
	100% Polyester	160415-002 160415-003 160512-001	<2.30 <2.30 <2.30	>99.9% >99.9% >99.9%	6.49

MRID # 501189-50	Lot #	7-day Evaluation	Evaluation of Test Carriers (percent %)									
			1	2	3	4	5	6	7	8	9	10
Aspergillus niger (ATCC 6275)	Control	Visual	70	90	85	75	75	80	95	100	100	95
	150611-001	Visual	0	0	0	0	0	0	0	0	0	0
		Magnified	-	-	-	-	-	-	-	-	-	-
	150611-002	Visual	0	0	0	0	0	0	0	0	0	0
		Magnified	-	-	-	-	-	-	-	-	-	-

MRID # 501189-51	Lot #	Evaluation of Test Carriers 1 to 10 (percent %)							
		Day 7		Day 14		Day 21		Day 28	
		Visual	Magnified	Visual	Magnified	Visual	Magnified	Visual	Magnified
Aspergillus niger (ATCC 6275)	Control	10+ (80-90)		10+ (100)		10+ (100)		10+ (100)	
	150409-001	0	0	1+ (1%)	+	0	0	1+ (1%)	+
	150611-001	0	0	0	0	0	0	0	0
Penicillium variabile (ATCC 32333)	Control	10+ (80-90)		10+ (100)		10+ (100)		10+ (100)	
	150409-001	0	0	1+ (1%)	+	0	0	1+ (1%)	+
	150611-001	0	0	0	0	0	0	0	0

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with bactericidal activity against the following microorganisms on hard, nonporous surfaces in the presence of a 5% organic soil load for the contact time specified below:

MRID	Organism	Contact Time
501189-15	*Staphylococcus aureus* (ATCC 6538)	1 min
501189-16	*Pseudomonas aeruginosa* (ATCC 15442)	55 sec.
501189-17	*Salmonella enterica* (ATCC 10708)	30 sec.
501189-18	*Acinetobacter baumannii* (MDR) (ATCC BAA-1605).	1 min
501189-19	Enterobacter aerogenes (ATCC 13048)	1 min
501189-20	*Enterococcus faecalis* (VRE) (ATCC 51575)	1 min
501189-21	*Escherichia coli* (ESBL) (ATCC BAA-196)	55 sec.
501189-22	*Escherichia coli* (O157:H7) (ATCC 35150)	1 min
501189-23	*Klebsiella pneumoniae* (CRE) (ATCC BAA-2146)	1 min
501189-24	*Staphylococcus aureus* (MRSA) (ATCC 33592)	1 min
501189-25	*Staphylococcus epidermidis* (MRSE) (ATCC 51625)	1 min
501189-26	*Staphylococcus aureus* (VRSA) (HIP11714)	1 min
501189-27	*Staphylococcus aureus* (VISA) (HIP5836)	1 min
501189-28	*Pseudomonas aeruginosa* MBL (CDC AR-0246/PSA-18)	55 sec.

2. The submitted efficacy data **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with fungicidal activity against the following microorganisms on hard, nonporous surfaces in the presence of a 5% organic soil load for the contact time specified below:

MRID	Organism	Contact Time
501189-29	*Trichophyton mentagrophytes* (ATCC 9533)	3 min
501189-30	*Aspergillus niger* (ATCC 6275)	3 min
501189-31	*Candida albicans* (ATCC 10231)	1 min

3. The submitted efficacy data **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with virucidal activity against the following microorganisms on hard, nonporous surfaces in the presence of a 5% organic soil load for the contact time specified below:

MRID	Organism	Contact time
501189-32	Duck Hepatitis B Virus, Strain 11/4/12 (as a surrogate for Human Hepatitis B Virus)	10 seconds
501189-33	Bovine Viral Diarrhea Virus (as a Surrogate Virus for Human Hepatitis C Virus)	10 seconds
501189-34	Herpes simplex virus type 1, Strain F(1) (ATCC VR-733)	10 seconds

501189-35	Herpes simplex virus type 2, Strain G (ATCC VR-734)	10 seconds
501189-36	Human Coronavirus, Strain 229E (ATCC VR-740)	10 seconds
501189-37	Human Immunodeficiency Virus type 1, Strain HTLV-III_B	10 seconds
501189-38	Avian Influenza A (H3N2) Reassortant virus, (ATCC VR-2072)	10 seconds
501189-39	2009-H1N1 Influenza A virus (Novel H1N1) Strain A/Mexico/4108/2009, (CDC #2009712192)	10 seconds
501189-40	F-9 strain of Feline Calicivirus (ATCC VR-782)	5 minutes
501189-41	Poliovirus type 1, Strain Chat (ATCC VR-1562)	4 min. 45 sec.
501189-42	Respiratory syncytial virus (RSV), Strain Long (ATCC VR-26)	10 seconds
501189-43	Rotavirus, Strain WA (ATCC VR-2018)	2 minutes

4. The submitted efficacy data (MRID 501189-44) **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* – BCG, on hard non-porous, non-food contact surfaces, in the presence of a 5% organic soil load, at room temperature for a 3 minute contact time.

5. The submitted efficacy data **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with 24-hour bacterial residual disinfection activity against the following microorganisms on hard, nonporous surfaces in the presence of a 5% organic soil load for the contact time specified below:

MRID	Organism	Contact Time
501189-45	*Enterobacter aerogenes* (ATCC 13048) *Pseudomonas aeruginosa* (ATCC 15442) *Staphylococcus aureus* (ATCC 6538)	4.5 minutes
501189-46	Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575)	4.5 minutes
501189-47	Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)	4.5 minutes

6. The submitted efficacy data (MRID 501189-48) **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a hard non-porous, non-food contact surface sanitizer for a 10 second contact time at room temperature

7. The submitted efficacy data (MRID 501189-49) **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a spot soft non-food contact surface sanitizer for a 10 second contact time at room temperature.

8. The submitted efficacy data (MRID 501189-50) **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with mildew fungistatic activities against *Aspergillus niger* (ATCC 6275) on visibly clean hard non porous surface for 7 days.

9. The submitted efficacy data (MRID 501189-51) **support** the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with mildew fungistatic activities against *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333) on visibly clean fabric.

Human Immunodeficiency Virus type 1, Strain HTLV-III_B	10 sec
Avian Influenza A (H3N2) Reassortant virus, (ATCC VR-2072)	10 sec
2009-H1N1 Influenza A virus (Novel H1N1) Strain A/Mexico/4108/2009, (CDC #2009712192)	10 sec
F-9 strain of Feline Calicivirus (ATCC VR-782)	5 min
Poliovirus type 1, Strain Chat (ATCC VR-1562)	5 min
Respiratory syncytial virus (RSV), Strain Long (ATCC VR-26)	10 sec
Rotavirus, Strain WA (ATCC VR-2018)	2 min

4. The proposed label claim is **acceptable** regarding the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with tuberculocidal activity (*Mycobacterium bovis* – BCG) on hard, non-porous surfaces in the presence of 5% organic soil, at room temperature, for a 3-minute contact time. This claim is supported by the applicant's data

5. The proposed label claims are **acceptable** regarding the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with sanitizing activity on hard non-porous, non-food contact surfaces against the following microorganisms in the presence of 5% organic soil, at room temperature, for a 10 second contact time. These claims are supported by the applicant's data:

Staphylococcus aureus (ATCC 6538)

Enterobacter aerogenes (ATCC 13048)

6. The proposed label claims are **acceptable** regarding the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with spot sanitizing activity on soft non-food contact surfaces against the following microorganisms in the presence of 5% organic soil, at room temperature, for a 10 seconds contact time. These claims are supported by the applicant's data:

Staphylococcus aureus (ATCC 6538)

Enterobacter aerogenes (ATCC 13048)

7. The proposed label claims are **acceptable** regarding the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with 24-hour residual disinfection activity for use on hard, non-porous surfaces against the following microorganisms in the presence of 5% organic soil, at room temperature, for a 5 minute contact time. These claims are supported by the applicant's data:

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575)

Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)

8. The proposed label claim is **acceptable** regarding the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with 7 days fungistatic activity, on visibly cleaned, hard non-porous surface. This claim is supported by the applicant's data

9. The proposed label claim is **acceptable** regarding the use of the product, Firebird F-130 (EPA File No. 42182-O), as a disinfectant with 7 days fungistatic activity, on visibly cleaned, fabric mildew fungistatic. This claim is supported by the applicant's data.

10. Make the following changes to the proposed label:

- Revise claims for *Trichophyton mentagrophytes* (ATCC 9533) to reflect the organism new name *Trichophyton interdigitale* (ATCC 9533).
- Revise claims for *Aspergillus niger* (ATCC 6275) to reflect the organism new name *Aspergillus brasiliensis* (ATCC 6275)
- Throughout the label the term "spot" is not an optional descriptor for "soft surface sanitization" claims, therefore remove the brackets indicating optional language.
- Throughout the label remove the terms "risk" and "hazard" in reference to cross-contamination.
- Throughout the label revise the 99.99% disinfection claims to read "99.9%" except for 24-hour residual disinfection claims (based on quantitative test with 5 $\log_{10}$ reduction).
- Throughout the label remove the term "treated" when intended to be a replacement for the word "wet." The term "treated" is not permitted to replace "wet" when describing application instructions.
- On page 3, under the direction for residual disinfection remove the term "wipe" as this process may remove product instead of allowing it to dry in place. The residual directions for this use should specify that once the product is applied the surface should remain wet for at least 5 minutes and then allowed to air dry. Also in this section remove the statement "No rinsing required" as it implies that rinsing after application is an option.
- On page 3, revise the current heading for the residual disinfection directions to read "For Residual Disinfection on Hard Non-Porous Surfaces for up to 24-hours:". In addition, this section should include the statements "Use of this product for residual disinfection should not alter standard cleaning and disinfection practices. If the treated surface is cleaned, reapplication of this product is necessary for continued residual activity."
- On page 6, remove the statement "First EPA registered long lasting disinfectant for healthcare."
- On pages 7, 9 and/or 10, remove all instances of the text "hospital acquired infections," "HAI's", "stop", "protection", "protects" and "deadly."
- On page 8, remove "Kills germs within 1 minute" as fungi (which have a 3-minute contact time) are part of the "germ" definition. Also on this page remove "...within 1 minute", "...less than 1 minute" and "1 minute or less", and also add "... on treated surfaces" to the cross-contamination claim.
- On page 9, remove the text "just simply spray and wipe germs away" as this is not consistent with the directions for use.
- On page 9, remove decontamination use reference as the product does not have instructions for this use.
- On pages 9 and 10, all language referring to residual disinfection, such as "sustained", "constant", "persistent', "continuing" and "enduring" should be qualified with "...up to 24-hours."
- On page 10, add "on treated surfaces" to "Keeps surfaces disinfected longer to [reduce] [stop] the spread of bacteria"
- On page 10 remove, the terms "antimicrobial",
- On page 10 and 17, remove Pseudomonas aeruginosa MBL (Metallo beta-lactamase positive) from the list (table) of organisms for residual disinfection claims because data were not submitted on that organism.
- On page 10, remove the claims referring to "touches" and "abrasions" as well as "normal wear and tear." These efficacy-related claims are ambiguous and subject to different interpretations.
- On page 11 add 'Spot Treatment" to "Soft Surface".

- On page 11, all residual mildewstat claims should indicate either "up to 7 days" or "for 7 days."
- On page 11, revise "...viral pathogen claims against:" to read "...viral pathogen claims against the following categories of emerging viral pathogens when used in accordance with the directions for use for Poliovirus type 1 or Norovirus:"

Rivas, Lorena

From: Laniyan, Ibrahim
Sent: Tuesday, August 01, 2017 6:12 AM
To: Rivas, Lorena
Cc: Grigsby, Stacey; Hardy, Jacqueline
Subject: RE: Hi Ibrahim, can you provide me the status on the efficacy review for this PRIA Reg. 42182-O Thank you!!!!
Attachments: I_Label_Firebird_F130_122216_lr.pdf

Good Morning Lorena,
Please see the following temporary label comments on PRIA Reg. 42182-O:

- Revise Claims for *Trichophyton mentagrophytes* (ATCC 9533) to reflect the organism new name *Trichophyton interdigitale* (ATCC 9533).
- Revise Claims for *Aspergillus niger* (ATCC 6275) to reflect the organism new name *Aspergillus brasiliensis* (ATCC 6275)
- All over the label, "**Spot**" is not an optional statement for "Soft Surface Sanitization": Remove brackets.
- Throughout the label revise the 99.99% disinfection claims to read "99.9%" except for 24 hour residual disinfection claims base on quantitative test with 5 $\log_{10}$ reduction.
- On page 3, Direction for Use for Residual Disinfection Claims, remove "**Wipe**" as it implies removal of product instead of drying product in place.
- On page 6, revise "**First EPA registered long lasting disinfectant for healthcare**".
- On page 8, remove "**Kills germs within 1 minute**" because fungi are part of the term "Germ" and they have 3-minute contact time.
- On page 10, add "**on treated surfaces**" to "Keeps surfaces disinfected longer to [reduce] [stop] the spread of bacteria"
- On pages 9 and 10, "**Remove Claims for Protecting someone**"
- On page 10 and 17, remove Pseudomonas aeruginosa MBL (Metallo beta-lactamase positive) from the list (table) of organisms for residual disinfection claims because data were not submitted on that organism
- On page 10, remove "**giving the ultimate peace of mind**" because it is a heightened statement.
- On page 11 add 'Spot Treatment" to "Soft Surface".

See also attached my highlighted revision of label

Thank you

Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division
Office of Pesticide Programs
1200 Pennsylvania Ave., NW (7510P)
Washington, DC 20460
Tel. (703) 308-0124
Fax (703) 308-8481

From: Rivas, Lorena
Sent: Tuesday, July 25, 2017 4:44 PM
To: Laniyan, Ibrahim <Laniyan.Ibrahim@epa.gov>
Subject: Hi Ibrahim, can you provide me the status on the efficacy review for this PRIA Reg. 42182-O Thank you!!!!

Decision #: 524654
DP #: (437784)
PRIA
Parent DP #:
Submission #: 996811
E-Sub #: 16351

D[illegible] PACKAGE BEAN SHEET

Date: 27-Jan-2017

* * * Registration Information * * *

Registration: 42182-O - Firebird F130

Company: 42182 - MICROBAN PRODUCTS COMPANY

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date: _____ PRIA Due Date: 13-Jun-2017 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: See page 3

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 27-Jan-2017 Due Back: _____

DP Ingredient: See page 3

DP Title: Product Chemistry

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	AD / PSB			Last Possible Science Due Date: 14-May-2017
Team Name:	CTT			Science Due Date:
Reviewer Name:	Tek, V.	2/7/17		Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

New Hospital Disinfectant
Electronic Submission: Pls go to Documentum for Info

Science Technical Screen Due Date: 2/20/2017
Please review CSFs (Basic and 2 alterantes) and data, MRID 50118901-50118907, for completeness

Data Evaluation
Please review CSFs and data to determine if they are acceptable to support this product's registration

DP#: (437784) *** Studies Sent for Review *** Decision#: (524654)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1550/Product Identity and composition	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1600/Description of materials used to produce the product	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1620/Description of production process	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1650/Description of formulation process	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1670/Discussion of formation of impurities	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1700/Preliminary analysis	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1750/Certified limits	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1800/Enforcement analytical method	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6302/Color	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6303/Physical state	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6304/Odor	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6314/Oxidizing or reducing action	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6315/Flammability	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.7000/pH	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.7100/Viscosity	Not Reviewed (23-Dec-2016)

DP#: (437734) *** Studies Sent for Review *** Decision#: (524654)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1550/Product Identity and composition	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1600/Description of materials used to produce the product	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1620/Description of production process	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1650/Description of formulation process	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1670/Discussion of formation of impurities	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1700/Preliminary analysis	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1750/Certified limits	Not Reviewed (23-Dec-2016)
50118901		Herber, T. (2016) Firebird F130: Product Chemistry: Identity, Composition, and Analysis. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 52p.	830.1800/Enforcement analytical method	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6302/Color	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6303/Physical state	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6304/Odor	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6314/Oxidizing or reducing action	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.6315/Flammability	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.7000/pH	Not Reviewed (23-Dec-2016)
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.7100/Viscosity	Not Reviewed (23-Dec-2016)

DP#: (437734) *** Studies Sent for Review *** Decision#: (524654)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50118902		Sanow, W. (2016) Firebird F-130: Product Chemistry Testing: Final Report. Project Number: A19784, SRC90031915/PCT/4. Unpublished study prepared by Accuratus Lab Services. 24p.	830.7300/Density/relative density	Not Reviewed (23-Dec-2016)
50118903		Sanow, W. (2016) Firebird F-130: Preliminary Analysis: Final Report. Project Number: A19783, SRC90031915/PCT/8, SRC90031915/PCT/1. Unpublished study prepared by Accuratus Lab Services. 39p.	830.1700/Preliminary analysis	Not Reviewed (23-Dec-2016)
50118904		Sanow, W. (2015) Microban F130: Enforcement Analytical Titration Validation for Chemical Characterization: Final Report. Project Number: A18255, SRC90031915/PCT/1. Unpublished study prepared by Accuratus Lab Services. 33p.	830.1800/Enforcement analytical method	Not Reviewed (23-Dec-2016)
50118905		Sanow, W. (2015) Microban F130: Enforcement GC Method Validation for Chemical Characterization: Final Report. Project Number: A18248, SRC90031915/PCT/2. Unpublished study prepared by Accuratus Lab Services. 35p.	830.1800/Enforcement analytical method	Not Reviewed (23-Dec-2016)
50118906		Sanow, W. (2016) Firebird F-130: Accelerated Storage Stability of Test Substances: Final Report. Project Number: A19131, SRC90080815/ACS. Unpublished study prepared by Accuratus Lab Services. 34p.	830.6317/Storage stability	Not Reviewed (23-Dec-2016)
50118906		Sanow, W. (2016) Firebird F-130: Accelerated Storage Stability of Test Substances: Final Report. Project Number: A19131, SRC90080815/ACS. Unpublished study prepared by Accuratus Lab Services. 34p.	830.6320/Corrosion characteristics	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.6313/Stability to normal and elevated temperatures, metals, and metal ions	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.6316/Explodability	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.6319/Miscibility	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.6321/Dielectric breakdown voltage	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7050/UV/Visible absorption	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7200/Melting point/melting range	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7220/Boiling point/boiling range	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7370/Dissociation constants in water	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7520/Particle size, fiber length, and diameter distribution	Not Reviewed (23-Dec-2016)

DP#: (437734) *** Studies Sent for Review *** Decision#: (524654)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7550/Partition coefficient (n-octanol/water), shake flask method	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7560/Partition coefficient (n-octanol/water), generator column method	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7570/Partition coefficient (n-octanol/water), estimation by liquid chromatography	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7840/Water solubility: Column elution method, shake flask method	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7860/Water solubility, generator column method	Not Reviewed (23-Dec-2016)
50118907		Herber, T. (2016) Firebird F130: Product Chemistry: Data Waivers. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 4p.	830.7950/Vapor pressure	Not Reviewed (23-Dec-2016)

)P#: (437734) *** Pro and Data Package Ingredients *** Decision#: (524654)

PC Code	CAS	Ingredient Name
)01501	64-17-5	Ethanol
)69105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)
)69149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride
)69165	32426-11-2	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride
)69166	5538-94-3	1-Octanaminium, N,N-dimethyl-N-octyl-, chloride
)69166	5538-94-3	1-Octanaminium, N,N-dimethyl-N-octyl-, chloride(.104%)
)69149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride(.104%)
)69165	32426-11-2	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride(.207%)
)69105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)(.276%)
)01501	64-17-5	Ethanol(68.61%)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

7/17/2017

SUBJECT: Product Chemistry Review for Firebird F130,
EPA Reg. No.: 42182-O, DP 437784

FROM: Vekalet Tek, Ph.D. Vekalet Tek
Product Science Branch, CT Team
Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Hardy, PM Team 34 / Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Registrant: Microban Products Company
Action code: A540
Agency Due Date: 8/13/2017
Science Due Date: 7/14/2017
Submission No.: 996811
E-Sub No.: 16351
Classification: EP
Process: Integrated system
Pesticide classification: Sanitizer

Group A MRID(s):50118901,50118903,50118904,50118905,50118907, **Group B MRID(s):** 50118902, 50118906, 50118907,

GUIDELINE(s): Series 830 Group A, Series 830 Group B

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
001501	64-17-5	Ethanol	68.61
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)	0.276
069165	32426-11-2	Octyl decyl dimethyl ammonium chloride	0.207
069149	7173-51-5	Didecyl dimethyl ammonium chloride	0.104
069166	5538-94-3	Dioctyl dimethyl ammonium chloride	0.104
		Other Ingredients	30.699
		Total	100%
Comments/Molecular Structure			

V. TEK 07/17/2017

I. BACKGROUND

The Registrant, Microban Products Company, has submitted an application for pesticide registration for their product: Firebird F130 EPA Reg. No. 42182-O and requested review of Group A and Group B data, and the proposed CSFs(Basic CSF, and Alternate CSF#1,2, dated 12/23/2016).

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-1 – Application for Pesticide Registration	☒	☐
EPA FORM 8570-27 – Formulator's Exemption Statement	☒	☐
EPA FORM 8570-34 – Certification with respect to citation of data	☒	☐
EPA FORM 8570-35 – Data Matrix (12/23/2016)	☒	☐
Cover letter (12/23/2016)	☒	☐
Transmittal document	☒	☐
Proposed CSF BASIC, (12/23/2016) and ALTERNATE CSF#1,2 (12/23/2016)	☒	☐
Proposed label, (Not indicated)	☒	☐
Certification for Pilot Fragrance Notification Program	☐	☒
	☐	☐
REFERENCED:	--	
Comments:		

III. FINDINGS

CONFIDENTIAL STATEMENT OF FORMULA

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	☐	☐	☐	☐	☒
Integrated	☐	☐	☒		

Active Ingredients(s)	Nominal	Upper limit	Lower limit
Ethanol	68.610%	70.67%	66.55%
Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)	0.276%	0.304%	0.248%
Octyl decyl dimethyl ammonium chloride	0.207%	0.228%	0.186%
Didecyl dimethyl ammonium chloride	0.104%	0.114%	0.093%

TEK

Dioctyl dimethyl ammonium chloride	0.104%	0.114%	0.093%
	Acceptable	**Not Acceptable**	**N/A**
1. The certified limits of all ingredients are within 40 CFR standard certified limits (**See Finding#3,4**).	☒	☐	☐
2. The nominal concentration(s) of the active ingredient is in agreement with the label.	☒	☐	☐
3. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	☒	☐	☐
4. All inert ingredients are approved for non-food use pesticide formulations.	☒	☐	☐
5. The impurities present >0.1% are identified.	☐	☐	☒
6. Impurities of toxicological significance have an upper certified limit.	☐	☐	☒

b. Product Label:

	Yes	**NO**	**N/A**
The formula contains one of the following:			
1. 10% or more of petroleum distillate	☐	☒	☐
2. 1.0% or more of methyl alcohol	☐	☐	☒
3. Sodium nitrite at any level	☐	☒	☐
4. A toxic list 1 inert at any level	☐	☒	☐
5. Arsenic in any form	☐	☒	☐
6. If yes to 2-6, then the inert ingredient list contains a relevant footnote	☐	☐	☒
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	☒	☐	☐
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	☒	☐	☐
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	☐	☐	☒

IV. Additional Findings

1. "Certificate of Analysis" for five batch analysis (see attached e-mail) and the production process (MRID# 50118901) of one of the A.I.s, ethanol (not from the EPA registered source), was provided and Guideline §830-1620 has met.

Product ingredient source information may be entitled to confidential treatment

Manufacturing process information may be entitled to confidential treatment

2. [redacted] have been justified (attached e-mail messages, dated 06/08/2017 and 06/27/2017) and approved for all three of the proposed CSFs, including Basic CSF, Alternate CSF#1,2, dated 12/23/2016.
3. [redacted] have been justified (MRID# 50118901 and e-mail message, dated 06/27/2017) and approved for all three of the proposed CSFs, including Basic CSF, Alternate CSF#1,2, dated 12/23/2016, herein.
4. "Quality Assurance Statement" and "Good Laboratory Practice Statement" for Preliminary Analysis Studies have been provided, MRID# 50118903.
5. Basic CSF and Alternate CSF#1,2, dated 12/23/2016, are acceptable.

Data Summary for Five Batch Analysis; Guideline §830.1700 (MRID# 50118903)

Test Substance: Firebird F-130				
Lot Number	**% Quaternary Ammonium**		**% Ethanol**	
	Average	Nominal	Average	Nominal
150611-04	0.661%	0.69%	69.578%	68.61 %
150611-05	0.663%		69.657%	
150611-06	0.657%		69.629%	
150611-07	0.649%		69.945%	
150611-08	0.653%		68.774%	

Table 2: Chemical Incompatibility Results (MRID# 50118902)

Material	Observation	
	Initial Observation	Final Observations/Reactions
Water (Reactivity evaluation with water)	No change at 25.5 °C	No change at 27.9 °C
Monoammonium Phosphate (Reactivity with fire extinguishing agents)	Partial dissolvation of the Reactant at 25.9 °C	Partial dissolvation of the reactant at 25.0 °C
Turpentine (Chemicals intended for household use)	Emulsion formed (immiscible) at 25.0 °C	Emulsion formed (immiscible) at 26.0 °C
Zinc (For reducing agents)	No change at 25.0 °C	No change at 25.5 °C
$KMnO_4$ (For oxidizing agents)	Partial separation of test substance and $KMnO_4$ at 24.9 °C	$KMnO_4$ settled at the bottom and small clumps of brown formed at 26.0 °C

According to the Study Director, "there were no circumstances that may have adversely affected the quality or integrity of the data"

V. TEK
07/17/2017

Data Summary for §830.6317 #Accelerated Storage Stability and §830.6320 @Corrosion Characteristics (MRID# 50118906)

Testing Sample: Firebird F-130				
Interval	**Avg. % Quaternary Ammonium**	**Avg.% Ethanol**	**Observation**	
			#Physical Changes	**@Corrosion Characteristics**
Initial (time 0)	0.66%	68.88 %	Analyst #1 and #2: "Liquid sample with no phase separation and no clamping"	There was no evidence of corrosion on the lids, liners, seams or slides of the container
After 14 Days at 54°C ± 2°C	0.67%	68.38%	Analyst #1 and #2: "Liquid sample with no phase separation and no clamping"	There was no evidence of corrosion on the lids, liners, seams or slides of the container

V. Conclusion

The Product Science Branch of The Antimicrobials Division finds, Basic CSF and Alternate CSFs#1,2, dated 12/23/2016, to be acceptable. The Series 830 Group A and Group B guidelines have been met.

VI. Table A:

Series 830 guidelines – Group A

OPPTS#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	50118901
830.1600	Description of materials	Acceptable	50118901
830.1620	Description of production process	Acceptable	50118901
830.1650	Description of formulation process	Acceptable	50118901
830.1670	Discussion of formation of impurities	Acceptable	50118901
830.1700	Preliminary analysis	Acceptable	50118903
830.1750	Certified limits	Acceptable	50118901 and Basic CSF
830.1800	Enforcement analytical method	Acceptable	50118904 and 50118905
830.1900	Submittal of samples	Waived -"Samples are available upon request"	50118907

VII. Table B:

Series 830 guidelines – Group B

OPPTS#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Clear	Acceptable	50118902
830.6303	Physical state	Liquid substance with no clumping nor phase separation	Acceptable	50118902
830.6304	Odor	Odor of alcohol	Acceptable	50118902
830.6313	Stability to normal & elevated temperatures, metals & metal ions	Product is not TGAI	Not applicable	50118907
830.6314	Oxidation/Reduction	No oxidizer/reducer present*	Acceptable	50118902
830.6315	Flammability	Flash Point 26.71 oC or 80.08 oF (Average)	Acceptable	50118902
830.6316	Explodability	Product does not contain explosive ingredients	Not applicable	50118907
830.6317	Storage stability	#Check Data Table-Findings	Acceptable	50118906
830.6319	Miscibility	Product not mixed with organic solvents	Not applicable	50118907
830.6320	Corrosion characteristics	@Check Data Table-Findings	Acceptable	50118906
830.6321	Dielectric breakdown voltage	Product not used near electrical equipment	Not applicable	50118907
830.7000	pH	8.59 (Average pH for the concentrated test sample)	Acceptable	50118902
830.7050	UV/Visible absorption	Not required for MUP or EP	Not applicable	50118907
830.7100	Viscosity	Kinematic viscosity=10.84 cSt Dynamic viscosity= 9.40 cP	Acceptable	50118902
830.7200	Melting point	Not required for liquid EP	Not applicable	50118907
830.7220	Boiling point	Not required for MUP or EP	Waived	50118902
830.7300	Density/relative	0.8672 g/ml (Average)=7.24 lb/gal	Acceptable	50118902
830.7370	Dissociation constants in water	Not required for MUP or EP	Not applicable	50118902
830.7520	Particle size	Not required for MUP or EP	Not applicable	N/A
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP or EP	Not applicable	N/A
830.7840/ 7860	Water solubility	Not required for MUP or EP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP or EP	Not applicable	N/A

Manufacturing process information may be entitled to confidential treatment

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	42182-x
	Product Name Firebird F130
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 12/23/2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

(069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C14 40% C12, 10%C16)
(069166) Dioctyl dimethyl ammonium chloride
(069149) Didecyl dimethyl ammonium chloride
(069165) Octyl decyl dimethyl ammonium chloride

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
(069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C14 40% C12, 10%C16) (069166) Dioctyl dimethyl ammonium chloride (069149) Didecyl dimethyl ammonium chloride (069165) Octyl decyl dimethyl ammonium chloride	[redacted]	[redacted]

Product ingredient source information may be entitled to confidential treatment

Signature	Name and Title	Date
Tony Herber	Tony Herber, Agent	12/23/2016

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Form Approved OMB No.2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Microban Products Company (704) 766-1086 11400 Vanstory Drive Huntersville, NC 28078	42182-x
Active Ingredient(s) and/or representative test compound(s) (1501) Ethanol	Date December 23, 2016
General Use Pattern(s) (list all those claimed for this product using 40CFR Part 158) Institutional, Healthcare, Residential non-food use disinfectant/sanitizer	Product Name Firebird F130

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix for should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (1) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Tony Herber	12/23/2016	Tony Herber, Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

therber@srcconsultants.com

From: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Sent: Wednesday, April 06, 2016 11:16 AM
To: therber@srcconsultants.com
Cc: rjones@srcconsultants.com
Subject: RE: efficacy volumes for a PRIA A540 registration

Good Morning, Tony

I apologize for the delay in providing a response to the amount of time efficacy needs to review a package with 25 or more studies. If your package contains 26-50 efficacy studies, the review time increases an additional 2 months, so a 2 month renegotiation request is needed. If your package contains 50+ studies, then the review time increases an additional 5 months, so a 5 month renegotiation request is needed.

If you have any questions, please contact me.

Regards,

Jacqueline Hardy

Jacqueline Hardy
Product Manager, Team 34
Antimicrobials Division (7510P)
U.S. Environmental Protection Agency
2777 South Crystal Drive
Arlington, VA 22202
Phone: (703) 308-6416

From: therber@srcconsultants.com [mailto:therber@srcconsultants.com]
Sent: Thursday, March 24, 2016 9:02 AM
To: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Cc: rjones@srcconsultants.com
Subject: efficacy volumes for a PRIA A540 registration

Hi Ms. Hardy,

I am working with a client to prepare an application for a new registration for an alcohol based disinfectant. I believe the application will qualify as a PRIA A540 review. From previous correspondence with the Agency we understand submission of more than 24 efficacy studies generally requires an extension to the 5 month PRIA timeline. Based on our current battery of efficacy testing, we are anticipating submitting between 36 – 46 efficacy studies with this application. For our planning purposes, can you tell me how long of an extension this would require? Would the submittal of 46 volumes be different than 36 volumes, or would the same extension duration apply in either situation?

Thank you in advance for your guidance, I look forward to your reply.

Regards,
Tony

Tony Herber

Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

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Tek, Vekalet

From: Tek, Vekalet
Sent: Tuesday, June 13, 2017 11:12 AM
To: Grigsby, Stacey
Subject: Firebird F130

Tracking:	**Recipient**	**Delivery**
	Grigsby, Stacey	Delivered: 6/13/2017 11:13 AM

Dear Stacey,

As I verbally told you a few minutes ago, last Friday, June 9, I called the registrant and talked with Mr. Tony Herber (Contact Info: therber@srconsultants.com, Phone:260-244-6270). He would contact the supplier or manufacturing company for the % composition with the certificate of analysis letter of one of the active ingredients in the proposed Basic CSF and provide it to me. So far, I haven't heard any from him. So, could you please contact him and remind the subject above?

Thank You!

Vekalet Tek

Vekalet Tek, Ph.D.
Chemistry
Product Science Branch
Antimicrobials Division
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202
E-mail: tek.vekalet@epa.gov
Phone:703-347-8160

Manufacturing process information may be entitled to confidential treatment

Tek, Vekalet

From: therber@srcconsultants.com
Sent: Wednesday, July 05, 2017 1:40 PM
To: Tek, Vekalet; Grigsby, Stacey
Subject: RE: Firefird F130, 42182-O
Attachments: GPC_confidential_Production_data_070317.xlsx

Dr. Tek and Stacey,

[redacted]

Please let me know if you would like to discuss this further.

Regards,
Tony

Tony Herber
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

SERVICE Portal, *a cloud-based gateway to state registration data.*
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From: Tek, Vekalet [mailto:tek.vekalet@epa.gov]
Sent: Wednesday, June 28, 2017 11:59 AM
To: therber@srcconsultants.com; Grigsby, Stacey
Subject: RE: Firefird F130, 42182-O

Hi Mr. Herber,

[redacted]

Should you have any questions or concerns regarding this subject, please feel free to contact me.

Thank You!

Vekalet Tek
Vekalet Tek, Ph.D.
Chemist
Product Science Branch
Antimicrobials Division
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202
E-mail: tek.vekalet@epa.gov
Phone:703-347-8160

From: therber@srcconsultants.com [mailto:therber@srcconsultants.com]
Sent: Tuesday, June 27, 2017 4:16 PM
To: Grigsby, Stacey <Grigsby.Stacey@epa.gov>; Tek, Vekalet <tek.vekalet@epa.gov>
Subject: RE: Firefird F130, 42182-O

Hi Stacey and Dr. Tek,

Please find attached the requested information:

1. Information on the purity of the [redacted]
2. Revised request for expanded certified limits for two components: [redacted]

Please let me know if you need any additional information.

Regards,
Tony

Tony Herber
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

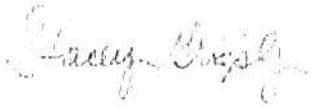
From: Grigsby, Stacey [mailto:Grigsby.Stacey@epa.gov]
Sent: Wednesday, June 21, 2017 8:17 AM

To: therber@srcconsultants.com; Tek, Vekalet
Subject: RE: Firefird F130, 42182-O

Sounds good Tony!

Thanks for your email and enjoy the rest of your day.

Sincerely,



Stacey Grigsby, Acting Product Manager, 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

From: therber@srcconsultants.com [mailto:therber@srcconsultants.com]
Sent: Wednesday, June 21, 2017 8:00 AM
To: Grigsby, Stacey <Grigsby.Stacey@epa.gov>; Tek, Vekalet <tek.vekalet@epa.gov>
Subject: Firefird F130, 42182-O

Good morning,

Stacey – I got your voicemail last night in regards to this product. I spoke with Dr. Tek last week, as there is a need to provide additional information about the ethanol in the product. I am working with the client to obtain this information from their ethanol supplier. I will send it to both of you as soon as I have it. Thank you!

Regards,
Tony

Tony Herber
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

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Pages 93-96 Manufacturing process information may be entitled to confidential treatment

Tek, Vekalet

From: therber@srcconsultants.com
Sent: Thursday, June 08, 2017 11:11 AM
To: Tek, Vekalet
Subject: 42182-X, Firebird F130

Hi Dr. Vekalet,

As we discussed on the phone a moment ago, the pH for the subject product was determined by sampling the undiluted product, rather than a 1% solution. Thank you.

Regards,
Tony

Tony Herber
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

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http://www.srcconsultants.com/services/service-portal

Manufacturing process information may be entitled to confidential treatment

Tek, Vekalet

From: therber@srcconsultants.com
Sent: Thursday, June 08, 2017 5:02 PM
To: Grigsby, Stacey; Tek, Vekalet
Subject: CSFs for 42182-O
Attachments: Da_CSF_Firebird_F130_BASIC_122316.pdf

Hi Stacey and Dr. Vekalet,

[redacted]

Please let me know if you have any questions/concerns or need more information regarding this. Thank you.

Regards,
Tony

Tony Herber
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

PRODUCT CHEMISTRY CHECKLIST FOR TECHNICAL SCREENS

42182-O_DP437784_Firebird F130.

1. The following are submitted or addressed for a complete product chemistry data package.

Group A – Product Identity, Composition, and Analysis Test Guidelines:

Pass__ 830.1550 Product identity and composition
Pass__ 830.1600 Description of materials used to produce the product
Pass__ 830.1620 Description of production process
Pass__ 830.1650 Description of formulation process
Pass__ 830.1670 Discussion of formation of impurities
Pass__ 830.1700 Preliminary analysis
Pass _ 830.1750 Certified limits
Pass _ 830.1800 Enforcement analytical method
Pass_ 830.1900 Submittal of samples ("Samples will be available upon request"- Data Waiver Request Form-Study Vol 7, MRID 50118907)

Group B – Physical/Chemical Properties Test Guidelines:

Pass __830.6302 Color
Pass __830.6303 Physical state
Pass __830.6304 Odor
N/A __ 830.6313 Stability to normal and elevated temperatures, metals, and metal ions (Not required for EUP- Data Waiver Request Form-Study Vol 7, MRID 50118907)
Pass _ 830.6314 Oxidation/reduction: chemical incompatibility
Pass _ 830.6315 Flammability
N/A_ 830.6316 Explodability ("Not required since the product is not potentially explosive"- Data Waiver Request Form-Study Vol 7, MRID 50118907)
Pass _ 830.6317 Storage stability
N/A _ 830.6319 Miscibility (Guideline 63-16-product is not intended to be diluted with petroleum solvents- Data Waiver Request Form-Study Vol 7, MRID 50118907)
Pass _830.6320 Corrosion characteristics
N/A _ 830.6321 Dielectric breakdown voltage (Guideline 63-17-product is not intended to be used around electrical equipment- Data Waiver Request Form-Study Vol 7, MRID 50118907)
Pass _ 830.7000 pH
N/A _ 830.7050 UV/Visible absorption (Not Required for EUP, Data Waiver Request Form-Study Vol 7, MRID 50118907)
Pass _ 830.7100 Viscosity
N/A _ 830.7200 Melting point/melting range (Guideline 63-9,20-product is not a solid TGAI-It is an EUP- Data Waiver Request Form-Study Vol 7, MRID 50118907)
N/A _ 830.7220 Boiling point/boiling range (Guideline 63-9,21-product is an EUP- Data Waiver Request Form-Study Vol 7, MRID 50118502)

Pass _	830.7300	Density/relative density/bulk density
N/A _	830.7370	Dissociation constants in water (Not Required since the product is an EUP- Data Waiver Request Form-Study Vol 7, MRID 50118502)
N/A _	830.7520	Particle size, fiber length, and diameter distribution
N/A _	830.7550	Partition coefficient (*n*-octanol/water), shake flask method
N/A _	830.7560	Partition coefficient (*n*-octanol/water), generator column method
N/A _	830.7570	Partition coefficient (*n*-octanol/water), estimation by liquid chromatography
N/A _	830.7840	Water solubility: Column elution method; shake flask method
N/A _	830.7860	Water solubility, generator column method
N/A_	830.7950	Vapor pressure

2. If the aforementioned studies are not applicable, indicate such (**i.e., N/A**) and a justification must be included.

   Fail__All studies must be addressed.
3. All studies must be submitted under GLP.
4. Include the most recent CSF and/or alternate CSF in the data package.
5. Signature must be included on the CSF.
6. Confirm that all pertinent items listed in the transmittal document are included.

NOTES:

PASSED----Pass Screen ----------Fail Screen

02/16/2017
Vekalet Tek, Ph.D.
Chemist

Tek, Vekalet

From: Tek, Vekalet
Sent: Thursday, February 16, 2017 11:49 AM
To: Hardy, Jacqueline (Hardy.Jacqueline@epa.gov)
Cc: Hicks, Karen; Rivas, Lorena (Rivas.Lorena@epa.gov)
Subject: 42182-O_DP437784_Firebird F130_TECHNICAL SCREEN PASSED
Attachments: 42182-O-Firebird F130-Technical Screen-PASSED.doc

Dear All,

From a chemistry point of view, at this time, the technical screen for Reg.# 42182-O_DP437784_Firebird F130_Microban Product Company have been **PASSED**, however, additional questions to be answered or data to be addressed may remain.

Thank you!

Vekalet Tek
Vekalet Tek, Ph.D.
Product Science Branch
Antimicrobials Division
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202
E-mail: tek.vekalet@epa.gov
Office Phone:703-347-8160

Tek, Vekalet

From: Tek, Vekalet
Sent: Wednesday, June 28, 2017 11:59 AM
To: 'therber@srcconsultants.com'; Grigsby, Stacey
Subject: RE: Firefird F130, 42182-O

Hi Mr. Herber,

[redacted]

Should you have any questions or concerns regarding this subject, please feel free to contact me.

Thank You!

Vekalet Tek
Vekalet Tek, Ph.D.
Chemist
Product Science Branch
Antimicrobials Division
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202
E-mail: tek.vekalet@epa.gov
Phone:703-347-8160

From: therber@srcconsultants.com [mailto:therber@srcconsultants.com]
Sent: Tuesday, June 27, 2017 4:16 PM
To: Grigsby, Stacey <Grigsby.Stacey@epa.gov>; Tek, Vekalet <tek.vekalet@epa.gov>
Subject: RE: Firefird F130, 42182-O

Hi Stacey and Dr. Tek,

Please find attached the requested information:

1. Information on the purity of the *Manufacturing process
2. Revised request for expanded certified limits for two components: *Manufacturing process information may be entitled to

Please let me know if you need any additional information.

Regards,
Tony

Tony Herber
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

Product ingredient source information may be entitled to confidential treatment

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http://www.srcconsultants.com/services/service-portal

From: Grigsby, Stacey [mailto:Grigsby.Stacey@epa.gov]
Sent: Wednesday, June 21, 2017 8:17 AM
To: therber@srcconsultants.com; Tek, Vekalet
Subject: RE: Firefird F130, 42182-O

Sounds good Tony!

Thanks for your email and enjoy the rest of your day.

Sincerely,

Stacey Grigsby, Acting Product Manager, 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

From: therber@srcconsultants.com [mailto:therber@srcconsultants.com]
Sent: Wednesday, June 21, 2017 8:00 AM
To: Grigsby, Stacey <Grigsby.Stacey@epa.gov>; Tek, Vekalet <tek.vekalet@epa.gov>
Subject: Firefird F130, 42182-O

Good morning,

Stacey – I got your voicemail last night in regards to this product. I spoke with Dr. Tek last week, as there is a need to provide additional information about the ethanol in the product. I am working with the client to obtain this information from their ethanol supplier. I will send it to both of you as soon as I have it. Thank you!

Regards,
Tony

Tony Herber
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201 W. Van Buren Street | Columbia City, IN 46725
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http://www.srcconsultants.com/services/service-portal

Manufacturing process information may be entitled to confidential treatment

Tek, Vekalet

From: therber@srcconsultants.com
Sent: Thursday, June 08, 2017 5:02 PM
To: Grigsby, Stacey; Tek, Vekalet
Subject: CSFs for 42182-O
Attachments: Da_CSF_Firebird_F130_BASIC_122316.pdf

Hi Stacey and Dr. Vekalet,

[redacted]

Please let me know if you have any questions/concerns or need more information regarding this. Thank you.

Regards,
Tony

Tony Herber
Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
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Pages 106-111 Product ingredient source information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date: December 23, 2016	EPA Reg. No./File Symbol: 42182-x	Page 1 of 9
Applicant's/Registrant's Name & Address: Microban Products Company, 11400 Vanstory Drive, Huntersville, NC 28078	Product: Firebird F130	

Ingredient: (069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550 (*61-1*)	Product Identity and Composition	50118901	Microban Products Company	OWN	
830.1600 (*61-2a*)	Description of Materials Used to Produce the Product	50118901	Microban Products Company	OWN	
830.1620 (*61-2b*)	Description of Production Process	50118901	Microban Products Company	OWN	
830.1650 (*61-2b*)	Description of Formulation Process	50118901	Microban Products Company	OWN	
830.1670 (*61-3*)	Discussion of Formation of Impurities	50118901	Microban Products Company	OWN	
830.1700 (*62-1*)	Preliminary Analysis	50118903	Microban Products Company	OWN	
830.1750 (*62-2*)	Certified Limits	50118901	Microban Products Company	OWN	
830.1800 (*62-3*)	Enforcement Analytical Method	50118904	Microban Products Company	OWN	
830.1800 (*62-3*)	Enforcement Analytical Method	50118905	Microban Products Company	OWN	
830.1900 [*64-1*]	Submittal of Samples	50118907	Microban Products Company	OWN	[1]
830.6302 (*63-2*)	Color	50118902	Microban Products Company	OWN	

[1] Available upon request

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date	December 23, 2016	EPA Reg. No./File Symbol	42182-x	Page 2 of 9
Applicant's/Registrant's Name & Address	Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	Product	Firebird F130	

Ingredient: (069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6303 (*63-3*)	Physical state	50118902	Microban Products Company	OWN	
830.6304 (*63-4*)	Odor	50118902	Microban Products Company	OWN	
830.6313 (*63-13*)	Stability to Normal and Elevated Temperature Metals and Metal Ions	50118907	Microban Products Company	OWN	[2]
830.6314 (*63-14*)	Oxidation /Reduction: Chemical Incompatibility	50118902	Microban Products Company	OWN	
830.6315 (*63-15*)	Flammability	50118902	Microban Products Company	OWN	
830.6316 (*63-16*)	Explodability	50118907	Microban Products Company	OWN	[3]
830.6317 (*63-17*)	Storage Stability	50118906	Microban Products Company	OWN	
830.6319 (*63-19*)	Miscibility	50118907	Microban Products Company	OWN	[4]
830.6320 (*63-20*)	Corrosion Characteristics	50118906	Microban Products Company	OWN	

[2] Not required: product is an End-Product (EP)
[3] Not required: product is not potentially explosive
[4] Not required: product is not for dissolution in petroleum solvents

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
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Form Approved OMB No. 2070-0060

DATA MATRIX

Date	December 23, 2016	EPA Reg. No./File Symbol	42182-x	Page 3 of 9
Applicant's/Registrant's Name & Address	Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	Product	Firebird F130	

Ingredient: (069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6321 (*63-21*)	Dielectric Breakdown Voltage	50118907	Microban Products Company	OWN	[5]
830.7000 (*63-12*)	pH	50118902	Microban Products Company	OWN	
830.7050 [*None*]	UV/Visible Absorption	50118907	Microban Products Company	OWN	[6]
830.7100(*63-18*)	Viscosity	50118902	Microban Products Company	OWN	
830.7200 (*63-5*)	Melting Point/ Melting Range	50118907	Microban Products Company	OWN	[6]
830.7220 (*63-6*)	Boiling Point/Boiling Range	50118907	Microban Products Company	OWN	[6]
830.7300 (*63-7*)	Density/ Relative Density/Bulk Density	50118902	Microban Products Company	OWN	
830.7370 (*63-10*)	Dissociation Constants in Water	50118907	Microban Products Company	OWN	[6]
830.7520 [*None*]	Particle Size Fiber Length and Diameter Distribution	50118907	Microban Products Company	OWN	[7]
830.7550 (*63-11*)	Partition Coefficient (*n*-Octanol/Water) Shake Flask Method	50118907	Microban Products Company	OWN	[6]

[5] Not required: product is not for use around electrical equipment
[6] Not required: Product is an End-Product (EP)
[7] Not required for liquid products

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

Form Approved OMB No. 2070-0060

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401 M. Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date	December 23, 2016	EPA Reg. No./File Symbol	42182-x	Page 4 of 9
Applicant's/Registrant's Name & Address	Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	Product	Firebird F130	

Ingredient: (069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7560 (*63-11*)	Partition Coefficient (*n*-Octanol/Water) Generator Column Method	50118907	Microban Products Company	OWN	[8]
830.7570 (*63-11*)	Partition Coefficient (*n*-Octanol/Water) Estimation By Liquid Chromatography	50118907	Microban Products Company	OWN	[8]
830.7840 (*63-8*)	Water Solubility: Column Elution Method; Shake Flask Method	50118907	Microban Products Company	OWN	[8]
830.7860 (*63-8*)	Water Solubility (Generator Column Method)	50118907	Microban Products Company	OWN	[8]
830.7950 (*63-9*)	Vapor Pressure	50118907	Microban Products Company	OWN	[8]
830 Series	Product Chemistry Data Waivers	50118907	Microban Products Company	OWN	
870.1100 (*81-1*)	Acute Oral Toxicity (UDP) in Rats; 19136-15	50118908	Microban Products Company	OWN	
870.1200 (*81-2*)	Acute Dermal Toxicity in Rats; 19137-15	50118909	Microban Products Company	OWN	
870.1300 (*81-3*)	Acute Inhalation Toxicity in Rats; 19138-15	50118910	Microban Products Company	OWN	
870.2400 (81-4)	Acute Eye Irritation in Rabbits; 19139-15	50118911	Microban Products Company	OWN	
870.2500 (*81-5*)	Acute Dermal Irritation in Rabbits; 19140-15	50118912	Microban Products Company	OWN	

[8] Not Required: Product is an End-Product (EP)

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

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401 M. Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date	December 23, 2016	EPA Reg. No./File Symbol	42182-x	Page 5 of 9
Applicant's/Registrant's Name & Address	Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	Product	Firebird F130	

Ingredient: (069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600 (*81-6*)	Dermal Sensitization in Guinea Pigs; 19141-15	50118913	Microban Products Company	OWN	
870 Series	Toxicity Discussion Volume	50118914	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test *Staphylococcus aureus* (ATCC 6538); GLP1573	50118915	Microban Products Company	OWN	
810.2200	AOAC Germicidal Spray Method *Pseudomonas aeruginosa* (ATCC 15442); A20096	50118916	Microban Products Company	OWN	
810.2200	AOAC Germicidal Spray Method *Salmonella enterica* (ATCC 10708); A20094	50118917	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test – *Acinetobacter baumannii* (MDR) (ATCC BAA-1605); GLP1479	50118918	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test – *Enterobacter aerogenes* (ATCC 13048); GLP1434	50118919	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test *Enterococcus faecalis* (VRE) (ATCC 51575); GLP1582	50118920	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test – *Escherichia coli* (ESBL) (ATCC BAA-196); GLP1478	50118921	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test – *Escherichia coli* O157:H7 (ATCC 35150); GLP1477	50118922	Microban Products Company	OWN	

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M. Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date	December 23, 2016	EPA Reg. No./File Symbol	42182-x	Page 6 of 9
Applicant's/Registrant's Name & Address	Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	Product	Firebird F130	

Ingredient (069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2200	GLP AOAC Germicidal Spray Products Test – *Klebsiella pneumoniae* (CRE) (ATCC BAA-2146); GLP1476	50118923	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test *Staphylococcus aureus* (MRSA) (ATCC 33592); GLP1583	50118924	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test *Staphylococcus epidermidis* (MRSE) (ATCC 51625); GLP1598	50118925	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test *Staphylococcus aureus* (VRSA) (HIP11714); GLP1599	50118926	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test *Staphylococcus aureus* (VISA) (HIP5836); GLP1600	50118927	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test – *Pseudomonas aeruginosa* (MBL) (CDC AR-0246/PSA-18); GLP1558	50118928	Microban Products Company	OWN	
810.2200	Fungicidal Germicidal Spray Method – *Trichophyton mentagrophytes* (ATCC 9533); A21241	50118929	Microban Products Company	OWN	
810.2200	Fungicidal Germicidal Spray Method – *Aspergillus niger* (ATCC 6275); A21500	50118930	Microban Products Company	OWN	
810.2200	GLP AOAC Germicidal Spray Products Test *Candida albicans* (ATCC 10231); GLP1596	50118931	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus; A20898	50118932	Microban Products Company	OWN	

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date	December 23, 2016	EPA Reg. No./File Symbol	42182-x	Page 7 of 9
Applicant's/Registrant's Name & Address	Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	Product	Firebird F130	

Ingredient: (069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus; A20925	50118933	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 1; A21016	50118934	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 2; A21015	50118935	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Coronavirus; A20995	50118936	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Immunodeficiency Virus type 1; A21002	50118937	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Avian Influenza A (H3N2) Reassortant virus; A20567	50118938	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – 2009-H1N1 Influenza A virus (Novel H1N1); A20994	50118939	Microban Products Company	OWN	

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

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DATA MATRIX

Date	December 23, 2016	EPA Reg. No./File Symbol	42182-x	Page 8 of 9
Applicant's/Registrant's Name & Address	Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	Product	Firebird F130	
Ingredient	(069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus; A20534	50118940	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Poliovirus type 1; A21684	50118941	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Respiratory syncytial virus (RSV); A21001	50118942	Microban Products Company	OWN	
810.2200	Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rotavirus; A21683	50118943	Microban Products Company	OWN	
810.2200	AOAC Tuberculocidal Activity of Disinfectant Spray Products – *Mycobacterium bovis* – BCG; A19362	50118944	Microban Products Company	OWN	
810.2200	Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – *Enterobacter aerogenes* (ATCC 13048), *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538); A19382	50118945	Microban Products Company	OWN	
810.2200	Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – *Enterococcus faecalis* – VRE (ATCC 51575); A19778	50118946	Microban Products Company	OWN	

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

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DATA MATRIX

Date	December 23, 2016	EPA Reg. No./File Symbol	42182-x	Page 9 of 9
Applicant's/Registrant's Name & Address	Microban Products Company 11400 Vanstory Drive Huntersville, NC 28078	Product	Firebird F130	

Ingredient: (069105) Alkyl* dimethyl benzyl ammonium chloride *(50% C_{14} 40% C_{12}, 10%C_{16}), (069166) Dioctyl dimethyl ammonium chloride, (069149) Didecyl dimethyl ammonium chloride, (069165) Octyl decyl dimethyl ammonium chloride, Ethanol (1501) (EP)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
810.2200	Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592); A19779	50118947	Microban Products Company	OWN	
810.2300	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application) – *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538); A21548	50118948	Microban Products Company	OWN	
810.2400	Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application) – *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538); A21260	50118949	Microban Products Company	OWN	
Subdivision G, 93-30	EPA Hard Surface Mildew-Fungistatic Test – *Aspergillus niger* (ATCC 6275); A20568	50118950	Microban Products Company	OWN	
Subdivision G, 93-30	Fabric Mildew Fungistatic Test – *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333); A20284	50118951	Microban Products Company	OWN	

Signature	Name and Title	Date
Tony Herber	Tony Herber , Agent	12/23/2016

Decision #: 524654
DP #: (437785)
PRIA
Parent DP #:
Submission #: 996811
E-Sub #: 16351

DATA PACKAGE BEAN SHEET

Date: 07-Feb-2017

* * * Registration Information * * *

Registration: 42182-O - Firebird F130

Company: 42182 - MICROBAN PRODUCTS COMPANY

Risk Manager: RM 34 - Jacqueline Hardy - (703) 308-6416 Room# PY1 S-8317

Risk Manager Reviewer: Lorena Rivas LRIVAS

Sent Date: _____ PRIA Due Date: 13-Jun-2017 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: See page 3

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 27-Jan-2017 Due Back: _____

DP Ingredient: See page 3

DP Title: Acute Toxicology

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #: _____

Assigned To		Date In	Date Out	
Organization:	AD / PSB			Last Possible Science Due Date: 14-May-2017
Team Name:	CTT			Science Due Date:
Reviewer Name:	Wallace	2/7/17		Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

New Hospital Disinfectant
Electronic Submission: Please go to Documentum for review

Science Techncial Screen Due Date: 2/20/2017
Please review the acute tox data for completeness, MRID 50118908-501189014

Data Evaluation
please review the acute tox data to determine the hazard language for the product label

DP#: (437785) *** Studies Sent for Review *** Decision#: (524654)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
50118908		Hartwell, T. (2016) Firebird F130: Acute Oral Toxicity (UDP) in Rats. Project Number: 19136/15, SRC90031915/PCT/3, A18718. Unpublished study prepared by Stillmeadow, Inc. 10p.	870.1100/Acute Oral Toxicity	Not Reviewed (23-Dec-2016)
50118909		Hartwell ,T. (2016) Firebird F130: Acute Dermal Toxicity in Rats. Project Number: 19137/15, A18718, SRC90031915/PCT/3. Unpublished study prepared by Stillmeadow, Inc. 11p.	870.1200/Acute dermal toxicity	Not Reviewed (23-Dec-2016)
50118910		Doig, A. (2016) Firebird F130: Acute Inhalation Toxicity in Rats. Project Number: 19138/15, A18718, SRC90031915/PCT/3. Unpublished study prepared by Stillmeadow, Inc. 17p.	870.1300/Acute inhalation toxicity	Not Reviewed (23-Dec-2016)
50118911		Hartwell, T. (2016) Firebird F130: Acute Eye Irritation in Rabbits. Project Number: 19139/15, A18718, SRC90031915/PCT/3. Unpublished study prepared by Stillmeadow, Inc. 14p.	870.2400/Acute eye irritation	Not Reviewed (23-Dec-2016)
50118912		Hartwell, T. (2016) Firebird F130: Acute Dermal Irritation in Rabbits. Project Number: 19140/15, A18718, SRC90031915/PCT/3. Unpublished study prepared by Stillmeadow, Inc. 11p.	870.2500/Acute dermal irritation	Not Reviewed (23-Dec-2016)
50118913		Hartwell, T. (2016) Firebird F130: Skin Sensitization in Guinea Pigs. Project Number: 19141/15, 18985/15, SRC90031915/PCT/3. Unpublished study prepared by Stillmeadow, Inc. 14p.	870.2600/Skin sensitization	Not Reviewed (23-Dec-2016)
50118914		Herber, T. (2016) Firebird F130: Toxicity Discussion Volume. Unpublished study prepared by Scientific & Regulatory Consultants, Inc. 6p.	870.2600/Skin sensitization	Not Reviewed (23-Dec-2016)

DP#: (437785) *** Product Data Package Ingredients *** Decision#: (524654)

PC Code	CAS	Ingredient Name
001501	64-17-5	Ethanol
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)
069149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride
069165	32426-11-2	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride
069166	5538-94-3	1-Octanaminium, N,N-dimethyl-N-octyl-, chloride
069166	5538-94-3	1-Octanaminium, N,N-dimethyl-N-octyl-, chloride(.104%)
069149	7173-51-5	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride(.104%)
069165	32426-11-2	1-Decanaminium, N,N-dimethyl-N-octyl-, chloride(.207%)
069105	68424-85-1	Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)(.276%)
001501	64-17-5	Ethanol(68.61%)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

MEMORANDUM

5/18/2017

SUBJECT: Acute Toxicity Review for Firebird F130, EPA Reg. No. 42182-O
DP 437785

FROM: Wallace Powell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Jenny Tao, Senior Scientist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Jacqueline Hardy, PM Team 34 / Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Registrant: Microban Products Company		
Decision No.: 524654	Submission No.: 996811	E-Sub No.: 16351
MRID No(s).: 50118908 through 50118913		

PC code	Active Ingredient	% weight
069105	Alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride	0.276
069165	Octyl decyl dimethyl ammonium chloride	0.207
069166	Dioctyl dimethyl ammonium chloride	0.104
069149	Didecyl dimethyl ammonium chloride	0.104
001501	Ethanol	68.610
	Other Ingredients	30.699
	Total	100.000

BACKGROUND

In support of registration for the proposed product *Firebird F130*, the applicant has submitted studies for acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, eye irritation, dermal irritation, and dermal sensitization. *Firebird F130* is a liquid, multi-use product for use on various surfaces and fabrics.

RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-1 – Application for Pesticide Registration	☒	☐
EPA FORM 8570-34 – Certification with respect to citation of data	☐	☒
EPA FORM 8570-35 – Data Matrix	☒	☐
Cover letter	☒	☐
Transmittal document	☒	☐
Basic CSF	☒	☐
Proposed label	☒	☐
Acute Oral Toxicity Study (OSCPP 870.1100)	☒	☐
Acute Dermal Toxicity Study (OSCPP 870.1200)	☒	☐
Acute Inhalation Toxicity Study (OSCPP 870.1300)	☒	☐
Primary Eye Irritation Study (OSCPP 870.2400)	☒	☐
Primary Skin Irritation Study (OSCPP 870.2500)	☒	☐
Dermal Sensitization Study (OSCPP 870.2600)	☒	☐

RECOMMENDATION

The six submitted studies are acceptable. A review of each study is attached to this memorandum. The MRIDs and the assigned Toxicity Categories are listed in the table below.

The acute toxicity profile for *Firebird F130* is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	50118908	IV	Acceptable
Acute Dermal Toxicity	50118909	IV	Acceptable
Acute Inhalation Toxicity	50118910	IV	Acceptable
Primary Eye Irritation	50118911	II	Acceptable
Primary Dermal Irritation	50118912	IV	Acceptable
Dermal Sensitization	50118913	Non-sensitizer	Acceptable

Product Labeling

The First Aid and human-hazard precautionary statements in the *Firebird F130* submitted labeling ("Version 122216") are in accordance with the Agency's *Label Review Manual* and are acceptable.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OCSPP 870.1100)

Product Manager: 34
MRID No.: 50118908

Reviewer: W. Powell
Study Completion Date: 2/2/2016
Report No.: 19136-15

Testing Laboratory: STILLMEADOW, Inc.
Author: Theresa A. Hartwell

Quality Assurance (40 CFR §160): Included

Test Material: Microban® Firebird F-130
Dose Level: 5000 mg/kg

Species: Rat, Sprague-Dawley
Sex: 3 Females
Age: Approximately 10-11weeks
Weight: 180-225 grams
Source: Texas Animal Specialties

Method: Up-and-Down Procedure. Limit test.

Summary:

1. **Estimated LD_{50}:** > 5000 mg/kg
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

Deviations from Guideline 870.1100 and related comments:

1. The relative humidity at times exceeded the recommendation in the Guidelines.

Results:

With administration of the test substance by oral gavage at a dose of 5000 mg per kg body weight to female rats in a stepwise manner, all three rats survived the 14-day observation period. Cage-side observations and gross necropsy revealed no notable findings. All three animals showed weekly weight gain.

Reported Mortality – Limit Test

Dosing Sequence	Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
1	5000	O	O
2	5000	O	O
3	5000	O	O

O = Survival

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OCSPP 870.1200)

Product Manager: 34
MRID No.: 50118909

Reviewer: W. Powell
Study Completion Date: 2/12/2016
Report No.: 19137-15

Testing Laboratory: STILLMEADOW, Inc.
Author: Theresa A. Hartwell

Quality Assurance (40 CFR §160): Included

Test Material: Microban® Firebird F-130
Dose Level: 5050 mg/kg

Animals: Rat, Sprague Dawley
Sex: 5 Males and 5 Females
Age: Approximately 9 weeks
Weight: Males: 256-302 g; Females: 174-212 g
Source: Texas Animals Specialties

Summary:

1. **Estimated LD_{50}:** > 5050 mg/kg
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

Deviations from Guideline 870.1200 and related comments:

1. The relative humidity at times exceeded the Guidelines.

Results:

Following a 24-hour exposure to the undiluted test substance at 5050 mg/kg, no animals died during the 14-day observation period. Cage-side observations and gross necropsy revealed no notable findings. All animals showed weekly weight gain except one female which lost 27 grams between Days 7 and 14.

Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Combined
5050	0 / 5	0 / 5	0 / 10

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OCSPP 870.1300)

Product Manager: 34
MRID No.: 50118910

Reviewer: W. Powell
Study Completion Date: 2/1/2016
Report No.: 19138-15

Testing Laboratory: STILLMEADOW, Inc.
Author: Andrew Doig

Quality Assurance (40 CFR §160): Included

Test Material: Microban® Firebird F-130
Concentrations: Gravimetric: 5.06 mg/L. Nominal: 4.80 mg/L
Chamber Type: Nose-only

Species: Rat, Sprague-Dawley
Sex: 5 Males and 5 Females
Age: Approximately 10 weeks
Weight: Males 293-360 grams, Females 198-216 grams
Source: Texas Animal Specialties

Summary:

1. **Estimated LC_{50}:** > 5.06 mg/L
2. **Toxicity Category:** IV
3. **Classification:** Acceptable

Deviations from Guideline 870.1300 and related comments:

1. The relative humidity in the animal room at times exceeded the Guidelines.

Results:

Following a 4-hour exposure, one animal of each sex died during the 14-day observation period. In-life clinical signs among surviving animals included diarrhea, nasal discharge, and stained muzzle, and all were limited to Day 1; decedent animals showed emaciation, labored breathing, lethargy, and nasal discharge. Post-mortem necropsy findings among the surviving animals were limited to lung discoloration (pale or mottled pale). Necropsy findings among the two decedent animals included red crusting around muzzle or nostrils, a withdrawn testicle, lung discoloration (dark red), black spot on liver, and gas in stomach and/or intestines.

Reported Mortality

Exposure Concentration (mg/L)	Number of deaths / number tested		
	Males	Females	Combined
5.06	1 / 5	1 / 5	2 / 10

Chamber Atmosphere

Exposure Conc. (mg/L)	MMAD (µm)	GSD	% of Particles < 3.8 µm
5.06	1.2	2.3	97.37

Chamber Environment

Exposure Level (mg/L)	5.06
Chamber Volume (L)	500
Total Airflow Rate (Lpm)	362
Temperature (°C)	21-22
Relative Humidity (%)	50

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

Product Manager: 34
MRID No.: 50118911

Reviewer: W. Powell
Study Completion Date: 2/12/2016
Report No.: 19139-15

Testing Laboratory: STILLMEADOW, Inc.
Author: Theresa A. Hartwell

Quality Assurance (40 CFR §160): Included

Test Material: Microban® Firebird F-130
Dosage: 0.1 mL

Species: Rabbit, New Zealand albino
Sex: 2 Males, 1 Female
Age: 13-16 weeks
Weight: 2.6 - 2.7 kg
Source: Veterinary Clinical Resources

Summary:

1. **Toxicity Category:** II
2. **Classification:** Acceptable

Deviations from Guideline 870.2400 and related comments: No deviations noted.

Results:

The table below provides the results ("positive" irritation) following instillation of 0.1 mL undiluted test material into the conjunctival sac of the right eye of three rabbits. Corneal opacity was noted in two rabbits at 1 hour after test material instillation, and in one rabbit thereafter, resolving by Day 14. No iridal effects were noted during the study. Positive conjunctival irritation (redness and/or chemosis scores ≥ 2) was noted in two to three rabbits at 1 hour and 24 hours after test material instillation, and in one rabbit thereafter, resolving by Day 14.

(Continued on next page)

Incidence of Irritation

Time Post-Instillation	No. of Animals Testing 'Positive' / No. of Animals Tested			
	Corneal Opacity	Iritis	Conjunctiva	
			Redness	Chemosis
1 hour	2 / 3	0 / 3	2 / 3	3 / 3
24 hours	1 / 3	0 / 3	3 / 3	2 / 3
48 hours	1 / 3	0 / 3	1 / 3	1 / 3
72 hours	1 / 3	0 / 3	1 / 3	1 / 3
Day 4	1 / 3	0 / 3	1 / 3	1 / 3
Day 7	1 / 3	0 / 3	1 / 3	0 / 3
Day 10	1 / 3	0 / 3	1 / 3	0 / 3
Day 14	0 / 3	0 / 3	0 / 3	0 / 3
Day 17	0 / 3	0 / 3	0 / 3	0 / 3
Day 21	0 / 3	0 / 3	0 / 3	0 / 3

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OCSPP 870.2500)

Product Manager: 34
MRID No.: 50118912

Reviewer: W. Powell
Study Completion Date: 2/2/2016
Report No.: 19140-15

Testing Laboratory: STILLMEADOW, Inc.
Author: Theresa A. Hartwell

Quality Assurance (40 CFR §160): Included

Test Material: Microban® Firebird F-130
Dosage: 0.5 mL

Species: Rabbit, New Zealand White
Sex: 1 Male, 2 Females
Age: 17-19 weeks
Weight: 2.6 - 3.2 kg
Source: Veterinary Clinical Resources

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Deviations from Guideline 870.2500 and related comments: No deviations noted.

Results:

The table below shows the erythema and edema results (individual Draize scores) following a four-hour dermal exposure in three rabbits.

No erythema, edema, or other signs of dermal irritation were observed at any treated site during the 72-hour observation period.

Individual Skin Irritation Scores following the four-hour exposure

Animal No.	Sex	Erythema / Edema			
		Time After Patch Removal			
		1 hour	24 hrs	48 hrs	72 hrs
467-F	F	0 / 0	0 / 0	0 / 0	0 / 0
546-M	M	0 / 0	0 / 0	0 / 0	0 / 0
469-F	F	0 / 0	0 / 0	0 / 0	0 / 0

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (OCSPP 870.2600)

Product Manager: 34
MRID No.: 50118913

Reviewer: W. Powell
Study Completion Date: 2/2/2016
Report No.: 19141-15

Testing Laboratory: STILLMEADOW, Inc.
Author: Theresa A. Hartwell

Quality Assurance (40 CFR §160): Included

Test Material:

Substance: Microban® Firebird F-130. 0.4 mL
Applied undiluted for induction and for challenge

Animals: Guinea pig, Hartley albino
Test group: 10 males, 9 females
Naïve control: 5 males, 5 females
Preliminary irritation testing: 2 males, 2 females

Historical Positive Control:

Substance: Alpha-Hexylcinnamaldehyde (85%). 0.4 mL
Applied undiluted for induction and for challenge

Animals: Guinea pig
Test group: 5 males, 5 females
Naïve control: 5 males, 5 females
Preliminary irritation testing: Not reported

Method: Buehler

Summary:

1. Microban® Firebird F-130 did **not** appear to be a contact sensitizer.
2. **Classification:** Acceptable

Deviations from Guideline 870.2600 and related comments:

1. Report seems to imply but does not actually state that the procedure narrative for the main study (Microban® Firebird F-130) applies to the Positive Control study also. (The report states, however, that the Positive Control study was conducted according to the Buehler Method.)
2. In the main study, one female test animal could not be located at the time of the third induction treatment (or any time thereafter).
3. In the main study, the relative humidity was at times outside Guideline range.
4. For Positive Control study, preliminary irritation testing results were not reported.

Results:

In the main study (Microban® Firebird F-130), no erythema was observed in the Test group following any of the induction applications nor challenge application; and no erythema was

observed in the Naïve Control group. The study results indicate that Microban® Firebird F-130 was **not** a contact sensitizer.

Historical Positive Control study results were appropriate. The Positive Control study was conducted within six months of the main (Microban® Firebird F-130) study.

Rivas, Lorena

From: Powell, Wallace
Sent: Wednesday, February 22, 2017 10:21 AM
To: Rivas, Lorena
Cc: Grigsby, Stacey; Hicks, Karen
Subject: Technical Screen - DP 437785 - 42182-O

Hi Lorena

The data package passes the screen and is ready to go into PSB review.

Wallace

Recommendation of Division Directors
Negotiated Due Dates

Decision #: 524654	Registration #: 42182-O	Petition #: N/A

☐ *See page 2 for additional registration entries*

Chemical Name: Firebird F130

Fee Category: A540 | **PRIA Decision Time Frame:** 5 months

Submitted by: Lorena Rivas | **Branch:** OCSPP/OPP/AD | **Date:** 02/08/2017

Company: Microban Products Company

Original PRIA Due Date: 06/13/2017 | **Proposed New PRIA Due Date:** 08/13/2017

Previous Negotiated Due Dates:

Is the "Fix" in-house? ☑ Yes ☐ No ☐ n/a | **If not, date "Fix" expected:**

Negotiated Due Date Reason:

Additional Data Required	☐ Product Chemistry	☐ Toxicology	☐ Acute Tox	☐ Environmental	
	☐ Efficacy	☐ Ecological	☐ Residue	☑ Other	
Data Deficiencies	☐ Product Chemistry	☐ Acute Tox	☐ Efficacy	☐ Residue	☐ Toxicology
	☐ Environmental	☐ Ecological	☐ Labeling	☐ Other	☐ Not Submitted
Late Risk Assessment	☐ Human Health	☐ Ecological			
Interim Consideration	☐ Agency Initiated	☐ Registrant Initiated			

☐ CSF	☐ Public Process	☐ Risk Issues Environmental	☐ Risk Issues Human Health
☐ Impurities Review	☐ Label	☐ Administrative-FR Notice	☑ Other – Comment Field

Summary of Deficiency Type(s): ☐ Not Submitted (N) ☐ Deficiencies (D)

Product Chemistry: ☐ **Acute Tox:** ☐ **Efficacy:** ☐ **Labeling:** ☐ **Ecological Data:** ☐ **Other (describe):** ☐

Registrant has requested a 2 month extension to compensate for the number of Efficacy studies.

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

Registrant contacted Agency on 3/24/2016, requesting a 2 month PRIA extension to compensate for the number of efficacy studies.

"75 Day" Letter sent? ☐ Yes, Date sent ☑ **No and reason for none?** *Add comments on page 2*

Rationale for Proposed Due Date: see comments on page 2

Registrant notified that this is the last negotiation? ☐ Yes ☑ Not Applicable

Approve: ☑ | **Disapprove:** ☐

If disapproved, action to be taken:

OD or DOD Signature: *CN=Richard Keigwin/OU=DC/O=USEPA/C=US* | **Date:** *02/09/2017*

Decision #: 524654	Registration #:42182-O	Petition #: N/A

Issue(s) (describe in detail):

BACKGROUND:
42182-O is an application to register new end use product Firebird F130, for use as a hard surface disinfectant with 24 hour residual disinfectant claims for use in healthcare settings. A non food contact surface sanitizer and sanitizer for soft (fabric) surfaces.

INTERNAL ISSUE:
The registrant has requested the Agency for a 2 month PRIA extension to compensate the 38 efficacy studies (MRID 50118915-50118951) which will increase additional review time to complete.

RECOMMENDATION:
Grant the 2 month PRIA extension due date to August 13, 2017, this will allow the Agency sufficient time to complete the reviews.

Comment(s):

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv5.pdf
Form Number: PRIA
Document Identifier: PRIA-17039105355-LR

SUBMITTED on 02/08/2017 at 04:30:31 PM by CN=Lorena Rivas/OU=DC/O=USEPA/C=US

APPROVED on 02/09/2017 at 07:01:57 AM by CN=Jose Gayoso/OU=DC/O=USEPA/C=US

APPROVED on 02/09/2017 at 07:55:54 AM by CN=Steve Knizner/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 02/09/2017 at 08:04:32 AM by CN=Richard Keigwin/OU=DC/O=USEPA/C=US

Attachment 1 – Correspondence with EPA (J. Hardy) – 2 month PRIA Extension

201 W Van Buren Street
Columbia City, IN 46725

www.srcconsultants.com

P: 260.244.6270
F: 260.244.6273

therber@srcconsultants.com

From: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Sent: Wednesday, April 06, 2016 11:16 AM
To: therber@srcconsultants.com
Cc: rjones@srcconsultants.com
Subject: RE: efficacy volumes for a PRIA A540 registration

Good Morning, Tony

I apologize for the delay in providing a response to the amount of time efficacy needs to review a package with 25 or more studies. If your package contains 26-50 efficacy studies, the review time increases an additional 2 months, so a 2 month renegotiation request is needed. If your package contains 50+ studies, then the review time increases an additional 5 months, so a 5 month renegotiation request is needed.

If you have any questions, please contact me.

Regards,

Jacqueline Hardy

Jacqueline Hardy
Product Manager, Team 34
Antimicrobials Division (7510P)
U.S. Environmental Protection Agency
2777 South Crystal Drive
Arlington, VA 22202
Phone: (703) 308-6416

From: therber@srcconsultants.com [mailto:therber@srcconsultants.com]
Sent: Thursday, March 24, 2016 9:02 AM
To: Hardy, Jacqueline <Hardy.Jacqueline@epa.gov>
Cc: rjones@srcconsultants.com
Subject: efficacy volumes for a PRIA A540 registration

Hi Ms. Hardy,

I am working with a client to prepare an application for a new registration for an alcohol based disinfectant. I believe the application will qualify as a PRIA A540 review. From previous correspondence with the Agency we understand submission of more than 24 efficacy studies generally requires an extension to the 5 month PRIA timeline. Based on our current battery of efficacy testing, we are anticipating submitting between 36 – 46 efficacy studies with this application. For our planning purposes, can you tell me how long of an extension this would require? Would the submittal of 46 volumes be different than 36 volumes, or would the same extension duration apply in either situation?

Thank you in advance for your guidance, I look forward to your reply.

Regards,
Tony

Tony Herber

Scientific & Regulatory Consultants, Inc.
201 W. Van Buren Street | Columbia City, IN 46725
www.srcconsultants.com | 260.244.6270

Introducing* SERVICE Portal*, a cloud-based gateway to state registration data.
http://www.srcconsultants.com/services/service-portal

Firebird F130

EPA File Symbol 42182-x

TRANSMITTAL DOCUMENT

1. Name and address of submitter:

   Scientific & Regulatory Consultants, Inc.
   201 W Van Buren Street
   Columbia City, IN 46725

   AGENT FOR:
   Microban Products Company
   11400 Vanstory Drive
   Huntersville, NC 28078

2. Regulatory action in support of which this package is submitted:
   New end use product; FIFRA §2(mm) uses only
   PRIA Code A540, PRIA fee $5,107

3. Transmittal date:

   December 23, 2016

4. Administrative materials:

   A) Cover letter
   B) Form 8570-1: Pesticide Application
   C) Pay.gov PRIA payment confirmation for $5,107 (Pay.gov ID 25VIOSC4)
   D) Form 8570-4: Confidential Statement of Formula: Basic and Alternates 1 & 2 dated 12/23/16
   E) Form 8570-27: Formulator's Exemption Statement
   F) Form 8570-34: Certification with Respect to Citation of Data (2)
   G) Form 8570-35: Data Matrix – End-Product (Agency and Public copies)
   H) Form 8570-35: Data Matrix – TGAI (Agency and Public copies)
   I) Proposed Master Label

5. Vol. 1 Product Chemistry (MRID 50118901)
   OCSPP 830.1550-1800 Product Chemistry: Identity, Composition, and Analysis

6. Vol. 2 Product Chemistry (MRID 50118902)
   OCSPP 830.6302-7300 Product Chemistry Testing; A19784

7. Vol. 3 Product Chemistry (MRID 50118903)
   OCSPP 830.1700 Preliminary Analysis; A19783

8. Vol. 4 Product Chemistry (MRID 50118904)
   OCSPP 830.1800 Enforcement Analytical Titration Validation for Chemical Characterization; A18255

9. Vol. 5 Product Chemistry (MRID 50118905)
   OCSPP 830.1800 Enforcement GC Method Validation for Chemical Characterization; A18248

10. Vol. 6 Product Chemistry (MRID 50118906)
    OCSPP 830.6317 & 830.6320 Accelerated Storage Stability of Test Substances; A19131

11. Vol. 7 Product Chemistry (MRID 50118907)
OCSPP 830 Series Product Chemistry Data Waivers

12. Vol. 8 Toxicity (MRID 50118908)
OCSPP 870.1100 Acute Oral Toxicity (UDP) in Rats; 19136-15

13. Vol. 9 Toxicity (MRID 50118909)
OCSPP 870.1200 Acute Dermal Toxicity in Rats; 19137-15

14. Vol. 10 Toxicity (MRID 50118910)
OCSPP 870.1300 Acute Inhalation Toxicity in Rats; 19138-15

15. Vol. 11 Toxicity (MRID 50118911)
OCSPP 870.2400 Acute Eye Irritation in Rabbits; 19139-15

16. Vol. 12 Toxicity (MRID 50118912)
OCSPP 870.2500 Acute Dermal Irritation in Rabbits; 19140-15

17. Vol. 13 Toxicity (MRID 50118913)
OCSPP 870.2600 Skin Sensitization in Guinea Pigs; 19141-15

18. Vol. 14 Toxicity (MRID 50118914)
OCSPP 870 Series Toxicity Discussion Volume

19. Vol. 15 Efficacy (MRID 50118915)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus aureus* (ATCC 6538); GLP1573

20. Vol. 16 Efficacy (MRID 50118916)
OCSPP 810.2200 AOAC Germicidal Spray Method – *Pseudomonas aeruginosa* (ATCC 15442); A20096

21. Vol. 17 Efficacy (MRID 50118917)
OCSPP 810.2200 AOAC Germicidal Spray Method – *Salmonella enterica* (ATCC 10708); A20094

22. Vol. 18 Efficacy (MRID 50118918)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Acinetobacter baumannii* (MDR) (ATCC BAA-1605); GLP1479

23. Vol. 19 Efficacy (MRID 50118919)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Enterobacter aerogenes* (ATCC 13048); GLP1434

24. Vol. 20 Efficacy (MRID 50118920)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Enterococcus faecalis* (VRE) (ATCC 51575); GLP1582

25. Vol. 21 Efficacy (MRID 50118921)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Escherichia coli* (ESBL) (ATCC BAA-196); GLP1478

26. Vol. 22 Efficacy (MRID 50118922)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Escherichia coli* (O157:H7) (ATCC 35150); GLP1477

27. Vol. 23 Efficacy (MRID 50118923)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Klebsiella pneumoniae* (CRE) (ATCC BAA-2146); GLP1476

28. Vol. 24 Efficacy (MRID 50118924)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus aureus* (MRSA) (ATCC 33592); GLP1583

29. Vol. 25 Efficacy (MRID 50118925)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus epidermidis* (MRSE) (ATCC 51625); GLP1598

30. Vol. 26 Efficacy (MRID 50118926)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus aureus* (VRSA) (HIP11714); GLP1599

31. Vol. 27 Efficacy (MRID 50118927)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Staphylococcus aureus* (VISA) (HIP5836); GLP1600

32. Vol. 28 Efficacy (MRID 50118928)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Pseudomonas aeruginosa* MBL (CDC AR-0246/PSA-18); GLP1558

33. Vol. 29 Efficacy (MRID 50118929)
OCSPP 810.2200 Fungicidal Germicidal Spray Method – *Trichophyton mentagrophytes* (ATCC 9533); A21241

34. Vol. 30 Efficacy (MRID 50118930)
OCSPP 810.2200 Fungicidal Germicidal Spray Method – *Aspergillus niger* (ATCC 6275); A21500

35. Vol. 31 Efficacy (MRID 50118931)
OCSPP 810.2200 GLP AOAC Germicidal Spray Products Test – *Candida albicans* (ATCC 10231); GLP1596

36. Vol. 32 Efficacy (MRID 50118932)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus; A20898

37. Vol. 33 Efficacy (MRID 50118933)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus; A20925

38. Vol. 34 Efficacy (MRID 50118934)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 1; A21016

39. Vol. 35 Efficacy (MRID 50118935)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Herpes simplex virus type 2; A21015

40. Vol. 36 Efficacy (MRID 50118936)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Coronavirus; A20995

41. Vol. 37 Efficacy (MRID 50118937)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Human Immunodeficiency Virus type 1; A21002

42. Vol. 38 Efficacy (MRID 50118938)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Avian Influenza A (H3N2) Reassortant virus; A20567

43. Vol. 39 Efficacy (MRID 50118939)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – 2009-H1N1 Influenza A virus (Novel H1N1); A20994

44. Vol. 40 Efficacy (MRID 50118940)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus; A20534

45. Vol. 41 Efficacy (MRID 50118941)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Poliovirus type 1; A21684

46. Vol. 42 Efficacy (MRID 50118942)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Respiratory syncytial virus (RSV); A21001

47. Vol. 43 Efficacy (MRID 50118943)
OCSPP 810.2200 Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Rotavirus; A21683

48. Vol. 44 Efficacy (MRID 50118944)
OCSPP 810.2200 AOAC Tuberculocidal Activity of Disinfectant Spray Products – *Mycobacterium bovis* - BCG; A19362

49. Vol. 45 Efficacy (MRID 50118945)
OCSPP 810.2200 Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – *Enterobacter aerogenes* (ATCC 13048), *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538); A19382

50. Vol. 46 Efficacy (MRID 50118946)
OCSPP 810.2200 Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575); A19778

51. Vol. 47 Efficacy (MRID 50118947)
OCSPP 810.2200 Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity – Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592); A19779

52. Vol. 48 Efficacy (MRID 50118948)
OCSPP 810.2300 Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application) – *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538); A21548

53. Vol. 49 Efficacy (MRID 50118949)
OCSPP 810.2400 Standard Test Method for Efficacy of Sanitizers Recommended for Soft Non-Food Contact Surfaces (Modification for Spray Product Application) – *Enterobacter aerogenes* (ATCC 13048) and *Staphylococcus aureus* (ATCC 6538); A21260

54. Vol. 50 Efficacy (MRID 50118950)
Subdivision G, 93-30 EPA Hard Surface Mildew-Fungistatic Test – *Aspergillus niger* (ATCC 6275); A20568

55. Vol. 51 Efficacy (MRID 50118951)
Subdivision G, 93-30 Fabric Mildew Fungistatic Test – *Aspergillus niger* (ATCC 6275) and *Penicillium variabile* (ATCC 32333); A20284

Company Official:	Tony Herber
Company Name:	Agent – Microban Products Company
Company Contact:	Tony Herber, Phone (260) 244-6270 Email: therber@srcconsultants.com

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060, Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [x] **Registration**
- [ ] **Amendment**
- [ ] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
42182-x	J. Hardy	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Firebird F130	34	

5. Name and Address of Applicant *(Include ZIP Code)*

Microban Products Company
11400 Vanstory Drive
Huntersville, NC 28078

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New product submission
PRIA Category: A540; new end-use product, existing chemical, requiring science review for product chemistry, acute toxicity, and efficacy.
PRIA Fee: $5,107 (Pay.gov ID 25VIOSC4); e-mail address: therber@srcconsultants.com, phone: 260.244.6270.
See cover letter for more details.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	16, 24, 32, 64 fl. oz., 1, 5, 55, 275 gal	[x] on label

6. Manner in Which Label is Affixed to Product: [x] Lithograph [x] Paper glued [ ] Stenciled [x] Other shrink sleeve, pressure sensitive

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Tony Herber	Agent	(260) 244-6270

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title	4. Typed Name	5. Date
Tony Herber	Agent	Tony Herber	12/23/2016

Lorena

21-Day Screen Completed by Contractor

21-Day Expires on 1-13-17

Jacket # 42182-0
MRID# 501189

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

JACQUELINE HARDY

Science Technical Screen Due Date: 2/20/2017
Technical Screen Due Date: 2/27/2017
Predecisional Due Date: 5/30/2017

42182-0

Memorandum

E-SUBMISSION

Date: 1 / 5 / 17

To: PM 34, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 04, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SCIENTIFIC & REGULATORY CONSULTANTS, INC.
MICROBAN PRODUCTS COMPANY
201 W. VAN BUREN STREET
COLUMBIA CITY, IN 46725

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 23-DEC-16. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-23-16

Experts In-Processing Signature: B.B. Date 12-27-16 Fee Paid: Yes ✓

Division management contacted on issues No _____ Yes _____ Date _____

EPA Reg. Number: 42182-O	EPA Receipt Date: 12-23-16

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	**yes** X	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes** X	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			
10	**<u>Required Data</u> and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments: Documentation: Pass

- Required forms are complete

Alverts: Pass

- Alverts approved for Non-food Use

PRN 11-3: Pass

MRID - 501189

AN 1/5/17 Overall Status: Pass

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

A540 - New end use product.

- Must submit or reference Group A and B product chemistry, toxicity, and/or efficacy data for each proposed product.
- Data waivers may be requested. Chemistry data on the TGAI in addition to the EP is required if an unregistered source is used.

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.1550	Product Identity & Composition	✓		
830.1600	Description of materials used to produce the product	✓		
830.1650	Description of formulation process	✓		
830.1670	Discussion on the formation of impurities	✓		
830.1700	Preliminary analysis	✓		
830.1750	Certified limits (158.345)	✓		
830.1800	Enforcement analytical method	✓		

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted	MP Data Submitted	TGAI Data Submitted
830.6302	Color	✓		
830.6303	Physical State	✓		
830.6304	Odor	✓		
830.6313	Stability to normal and elevated temperatures metal and metal ions			
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓		
830.6315	Flammability	✓		
830.6316	Explodability	✓		
830.6317	Storage stability*	✓		
830.6319	Miscibility	✓		
830.6320	Corrosion Characteristics*	✓		
830.6321	Dielectric Breakdown Voltage	✓		
830.7000	pH	✓		
830.7050	UV/ Visible Absorption			
830.7100	Viscosity	✓		
830.7200	Melting Point			
830.7220	Boiling Point			
830.7300	Density	✓		
830.7370	Dissociation Constant			
830.7550	Partition Coefficient			
830.7840	Water Solubility			
830.7950	Vapor Pressure			

Grayed out = data not required *May not be included with initial application

A540 – Acute Toxicity Requirements

New products must either:
1) supply the product specific acute toxicity 6 pack data (listed below),
2) provide a bridging rationale document or waiver request or,
3) use the cite all method of data compensation, if applicable. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cite All	Selective	Waiver Request	Bridging Rational
830.1100	Acute Oral (LD50)	✓			
830.1200	Acute Dermal (LD50)	✓			
830.1300	Acute Inhalation (LC50)	✓			
830.2400	Acute Eye Irritation	✓			
830.2500	Acute Dermal Irritation	✓			
830.2600	Dermal Sensitization	✓			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 27, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-524654
EPA File Symbol or Registration Number: 42182-O
Product Name: Firebird F130
EPA Receipt Date: 23-Dec-2016
EPA Company Number: 42182
Company Name: MICROBAN PRODUCTS COMPANY

TONY HERBER
SCIENTIFIC & REGULATORY CONSULTANTS, INC.
AGENT FOR MICROBAN PRODUCTS COMPANY
201 W. VAN BUREN STREET
COLUMBIA CITY, IN 46725-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8154.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

PRISM Documentum

Inbox
Basic Search
Advanced Search
Categories Search
My Saved Searches
My Checkout
Import Internal
Import External

Log Off

Supporting Docs
- User Guide
- Document Types Guide

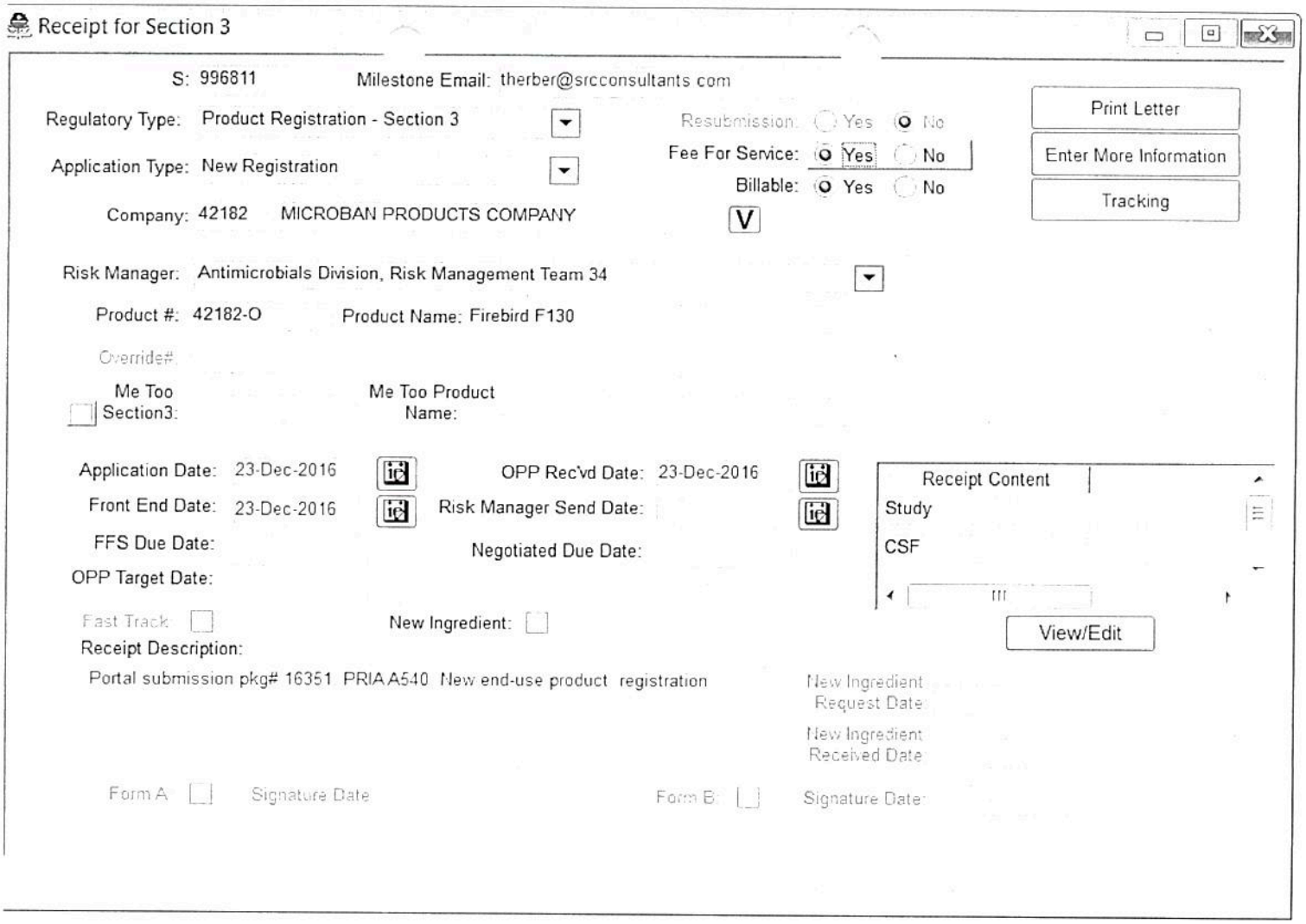
Info Comments Progress

ISB In Processing : 42182-O S996811 2016-12-23
Description: 42182-O S996811 2016-12-23
From: Doc Admin
Received: 12/23/2016 1:31 PM
WorkFlow Instructions:

cd_16351_996811 : Comments

Comment	Author	Date
PRIA / A540 / $3,107.00	Grigsby, Stacey	12/23/2016 1:31 PM

Add


Receipt for Section 3
S: 996811
Milestone Email: therber@srcconsultants com
Regulatory Type: Product Registration - Section 3
Application Type: New Registration
Company: 42182 MICROBAN PRODUCTS COMPANY
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 42182-O
Product Name: Firebird F130
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 23-Dec-2016
OPP Rec'vd Date: 23-Dec-2016
Front End Date: 23-Dec-2016
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Portal submission pkg# 16351 PRIA A540 New end-use product registration
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

therber@srcconsultants.com

From: notification@pay.gov
Sent: Friday, December 16, 2016 9:01 AM
To: therber@srcconsultants.com
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25VIOSC4
Agency Tracking ID: 75148363880
Transaction Type: Sale
Transaction Date: 12/16/2016 09:00:59 AM EST

Account Holder Name: Rebecca Drzal

Transaction Amount: $5,107.00
Card Type: MasterCard
Card Number: **********0119

Registration Number:
Company Name: Microban Products Company
Company Number: 42182
Action Code: A540

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Pages 163-174 Confidential Statement of Formula may be entitled to confidential treatment